

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

Printing date 07.06.2018

Revision: 30.04.2018

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

- **Product identifier**
- **Trade name:** OpalDam®
- **Article number:** 32103
- **Index number:** SDS 2-001.11
- **Relevant identified uses of the substance or mixture and uses advised against**  
Professional Light Cure Resin Barrier
- **Application of the substance / the mixture** Professional Light Cure Resin Barrier
- **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

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

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008**  
The product is classified and labelled according to the CLP regulation.
- **Hazard pictograms**



GHS07

- **Signal word** Warning
- **Hazard-determining components of labelling:**  
DUDMA  
2-Dimethylaminoethyl Methacrylate

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- **Hazard statements**  
H317 May cause an allergic skin reaction.
- **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.  
P362+P364 Take off contaminated clothing and wash it before reuse.  
P333+P313 If skin irritation or rash occurs: Get medical advice/attention.  
P321 Specific treatment (see on this label).  
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: 72869-86-4	DUDMA	>50-≤100%
EINECS: 276-957-5	⚠ Skin Sens. 1, H317	
CAS: 112926-00-8	Synthetic Amorphous Silica	>2.5-≤10%
EC number: 601-214-2	⚠ Acute Tox. 3, H331	
CAS: 2867-47-2	2-Dimethylaminoethyl Methacrylate	≤2.5%
EINECS: 220-688-8	⚠ Acute Tox. 4, H302; Acute Tox. 4, H312; Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317	

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

### 4 First aid measures

- **Description of first aid measures**
- **After inhalation:**  
Seek medical treatment in case of complaints.  
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.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult doctor.
- **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:** Use fire extinguishing methods suitable to surrounding conditions.

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- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **Protective equipment:** No special measures required.

## 6 Accidental release measures

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **Environmental precautions:** No special measures required.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **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** No special precautions are necessary if used correctly.
- **Information about fire - and explosion protection:** No special measures required.
- **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.
- **Specific end use(s)** Professional Light Cure Resin Barrier

## 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:**  
Immediately remove all soiled and contaminated clothing  
Wash hands before breaks and at the end of work.
- **Respiratory protection:** Not required.
- **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.

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*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.*

- **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:** Goggles recommended during refilling

- **Body protection:** Protective work clothing

## 9 Physical and chemical properties

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

- **General Information**

- **Appearance:**

**Form:** Viscous Liquid

**Colour:** Yellow tint

- **Odour:** Acrylic

- **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 at 20 °C:** 1.11 g/cm<sup>3</sup>

- **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** No further relevant information available.
- **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** No further relevant information available.
- **Incompatible materials:** No further relevant information available.
- **Hazardous decomposition products:** No dangerous decomposition products known.

## 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)**

Inhalative	LC50/4 h	>17.3 mg/l (rat)
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**72869-86-4 DUDMA**

Oral	LD50	>5,000 mg/kg (rat)
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**112926-00-8 Synthetic Amorphous Silica**

Oral	LD50	>5,000 mg/kg (rat)
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Dermal	LD50	>5,000 mg/kg (rabbit)
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Inhalative	LC50/4 h	>0.69 mg/l (rat)
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**2867-47-2 2-Dimethylaminoethyl Methacrylate**

Oral	LD50	1,550 mg/kg (rat)
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	LC50 Fish	19 mg/l (Fish)
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Dermal	LD50	2,000 mg/kg (rabbit)
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Inhalative	LC50/4 h	96 mg/l (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** Based on available data, the classification criteria are not met.
- **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.

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### 12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**

**72869-86-4 DUDMA**

EC50	>0.6 mg/l (Algae) (Toxicity to algae)
	>1.2 mg/l (daphnia) (Toxicity to aquatic invertebrates)

**2867-47-2 2-Dimethylaminoethyl Methacrylate**

EC50	42 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:** Not known to be hazardous to water.

· **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**

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

· **European waste catalogue**

HP 13	Sensitising
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· **Uncleaned packaging:**

· **Recommendation:** Disposal must be made according to official regulations.

### 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.

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- |   |                        |
|---|------------------------|
| <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**

H302 Harmful if swallowed.  
 H312 Harmful in contact with skin.  
 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  
 Acute Tox. 4: Acute toxicity – Category 4  
 Acute Tox. 3: Acute toxicity – Category 3  
 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