

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/cm³

· **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)
Dermal	LD50	>5,000 mg/kg (rabbit)
Inhalative	LC50/4 h	>0.69 mg/l (rat)

2867-47-2 2-Dimethylaminoethyl Methacrylate

Oral	LD50	1,550 mg/kg (rat)
	LC50 Fish	19 mg/l (Fish)
Dermal	LD50	2,000 mg/kg (rabbit)
Inhalative	LC50/4 h	96 mg/l (rat)

- **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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- | | |
|---|-----------------|
| · 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**
- **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