

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 08/14/2012

SDS No : 2-001.9

Date Revised : 04/15/2015

Revision No : 12

OpalDam®**SECTION 1 : Identification of the substance/preparation and of the company/undertaking****1.1. Product identifier**

Product code : DM/32103
Product name : OpalDam®
Product description : Light cured resin barrier

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses : Professional Light Cure Resin Barrier

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 : R36/38

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

Health : Eye Irritation
 Skin Irritation

2.2. Label elements**Classification according to Directive 1999/45/EC**

Hazard pictogram(s) : Xi



Irritant

R&S statement(s) : R36/38: Irritating to eyes and skin.

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

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ULTRADENT
 PRODUCTS, INC.

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Hazard pictogram(s)



Exclamation
 mark

Signal Word

: WARNING

Hazard statement(s)

: H315: Causes skin irritation.

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

: P273: Avoid release to the environment.

Disposal

: P501: Dispose of in compliance with governmental regulation(EC 1975L0442-20/11/2003).

2.3. Other hazards

Immediate concerns

: None

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt.%	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Cetyl Alcohol	36653-82-4	253-149-0	< 15	Xi; R36/37/38	H335; H315; H319; H412
Diurethane Dimethacrylate	72869-86-4	276-957-5	< 90	Xi; R36/37/38	H317; H319; H411; H315; H335

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.

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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. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

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

Eyes : Irritating to eyes.
Skin : Causes skin irritation.
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
Fire explosion : Not Determined
Sensitive to static discharge : Not Determined
Sensitivity to impact : Not Determined

5.3. Advice for firefighters

Fire fighting procedures : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.
Fire fighting equipment : Water spray, fog, or mist, foam, dry chemical, carbon dioxide(CO₂)

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 : Do not allow to enter sewers or drains that may lead to waterways.

6.3. Methods and material for containment and cleaning up

Small spill : Wipe up small amounts with chemical resistant or damp rag which is washed with large amounts of water after each use. After cleaning, flush away traces with water.
Large spill : Collect in tightly closed containers.

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Reference to other sections : Not Applicable

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Handling : Keep away from heat sources and direct sunlight.

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 Light Cure Resin Barrier

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**9.1. Information on basic physical and chemical properties**

Physical state : Viscous substance

Colour : White to light yellow

Odour : Acrylic

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity**10.1. Reactivity**

Reactivity : Polymerization occurs when exposed to visible light, ultraviolet light or extreme heat.

10.2. Chemical stability

Chemical stability : Stable when stored and handled under recommended conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization : None

10.4. Conditions to avoid

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Conditions to avoid : Strong oxidizing agents

10.5. Incompatible materials

Incompatible materials : Strong oxidizing agents

10.6. Hazardous decomposition products

Hazardous decomposition products : None known.

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.

SECTION 12: Ecological information

12.1. Toxicity

Toxicity : Water pollutant

Aquatic toxicity (acute)

96-hour LC₅₀ : Not Determined

48-hour EC₅₀ : Not Determined

96-hour EC₅₀ : Not Determined

12.2. Persistence and degradability

Persistence and degradability : Not Determined

12.3. Bioaccumulative potential

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 readily degradable.

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

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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 : Not Dangerous Goods

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

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.
 H315: Causes skin irritation.
 H317: May cause an allergic skin reaction.
 H319: Causes serious eye irritation.
 H335: May cause respiratory irritation.
 H411: Toxic to aquatic life with long lasting effects.
 H412: Harmful to aquatic life with long lasting effects.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 12/23/2014 SDS. Revised: **Section 1:**
 . **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - SKIN. **Section 10:** HAZARDOUS POLYMERIZATION, INCOMPATIBLE MATERIALS, STABLE, POSSIBILITY OF HAZARDOUS REACTIONS. **Section 11:** ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat) ACUTE. **Section 15:** SECTION 15: Regulatory

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