SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use

ULTRADENT PRODUCTS, INC.

Date Issued : 08/14/2012
SDS No : 2-001.10
Date Revised : 09/16/2016
Revision No : 13

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

EC Responsible Person

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 : Skin Sensitization, Category 1
Acute Toxicity (Inhalation), Category 4

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : Xi

Irritant

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

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

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Hazard pictogram(s) :

Exclamation mark

Signal Word : WARNING

Hazard statement(s) : H317: May cause an allergic skin reaction.
H335: May cause respiratory 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.
P337+P313: If eye irritation persists: Get medical advice/attention.
P302+P352: IF ON SKIN: Wash with plenty of soap and water.
P333+P313: If skin irritation or rash occurs: Get medical advice/attention.
P285: In case of inadequate ventilation wear respiratory protection.

Storage : P273: Avoid release to the environment.

Disposal : P501: Dispose of in compliance with governmental regulation. (EC1975L0442-20/11/2003)

2.3. Other hazards

Conclusion The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

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	Not classified
Diurethane Dimethacrylate	72869-86-4	276-957-5	< 90	Xi; R36/37/38	Skin Sens.,Cat. 1; H317
Titanium Dioxide	13463-67-7	236-675-5	< 1	Xi; R36/37/38; R22	Not classified

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 eyes with water. Get medical attention if irritation develops or persists.

Following skin : Wash with soap and water. Get medical attention if irritation develops or

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persists.

Following ingestion : No special measures required.

Following inhalation : Rest in the fresh air and seek medical advice if necessary.

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

Eyes : May be mildly irritating to eyes.

Skin : Causes skin irritation and sensitization.

Ingestion : None expected for this product.

Inhalation : May cause mild irritation.

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 : Water spray, fog, or mist, foam, dry chemical, carbon dioxide(CO_2)

5.2. Special hazards arising from the substance or mixture

Hazardous combustion products : None known.

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.

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.

6.4. Reference to other sections

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

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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 : Titanium Dioxide CAS: 13463-67-7

Control Parameters	Exposure Limits
NIOSH REL	Ca See Appendix A
OSHA PEL General Industry	15 mg/m3 TWA
ACGIH TLV	10 mg/m3 TWA

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

Specific gravity : 1.1 to 1.2

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

Conditions to avoid : Visible light, ultraviolet light, and extreme heat

10.5. Incompatible materials

Incompatible materials : Strong oxidizing agents

10.6. Hazardous decomposition products

Hazardous decomposition products : None known.

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SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Dermal LD_{50} : > 2900 mg/kg(Rabbit/Rat)

Notes : ~60% of the mixture consists of components of unknown toxicity (dermal).

Oral LD_{50} : > 4300 mg/kg (Rat)

Notes : There are no components of unknown toxicity (Oral).

Inhalation LC_{50} : > 2 mg/L/4H Vapor Rat

Notes : ~95% of the mixture consists of components of unknown toxicity (Inhalation)

Other information : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity (acute) : Do not allow to enter sewers or drains that may lead to waterways.

12.2. Persistence and degradability

Persistence and degradability : Not classified

12.3. Bioaccumulative potential

Bioaccumulative potential : Not classified

12.4. Mobility in soil

Mobility in soil : Not Available

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Conclusion The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

12.6. Other adverse effects

Environmental data : Do not flush to sewer.

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

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)

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Hazard classification	**:** NAP

14.4. Packing group

Packing group	**:** NAP

14.5. Environmental hazards

Marine pollutant #1	**:** NAP

14.6. Special precautions for user

ADR - road	**:** NAP
RID - rail	**:** NAP
IMDG - sea	**:** NAP
IATA - air	**:** NAP

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk	**:** NAP

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

General Information	**:** Please refer to Medical Devices Directive 93/42/EEC

15.2. Chemical safety assessment

Chemical safety assessment	**:** See Section 11
Additional information	**:** Titanium Dioxide has been classified as a group 2B(possible human carcinogen), per IARC monograph. However this product offers a low possibility of inhalation since it is not a powder or dried form. This product is not considered dangerous for transportation.

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text)	**:** R22: Harmful if swallowed. R36/37/38: Irritating to eyes, respiratory system and skin. Skin Sens., Cat. 1: Skin Sensitization, Category 1 H317: May cause an allergic skin reaction.
Prepared by	**:** Anu Kattoju
Revision summary	**:** This SDS replaces the 04/15/2015 SDS. Revised: **Section 1:** MSDS No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 4:** EYES, INHALATION, SIGNS AND SYMPTOMS OF OVEREXPOSURE (INHALATION, SKIN), SKIN. **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 8:** . **Section 9:** SPECIFIC GRAVITY. **Section 10:** CONDITIONS TO AVOID. **Section 11:** ACUTE (DERMAL LD_{50} (rabbit), DERMAL LD_{50} (rabbit), DERMAL LD_{50} (rabbit), ORAL LD_{50} (rat), INHALATION LC_{50} (rat), ORAL LD_{50} (rat), ORAL LD_{50} (rat), INHALATION LC_{50} (rat), INHALATION LC_{50} (rat), INHALATION LC_{50} (rat), ORAL LD_{50} (rat) ACUTE, GENERAL COMMENTS. **Section 12:** CHEMICAL FATE INFORMATION,

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	DISTRIBUTION, ECOTOXICOLOGICAL INFORMATION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), AQUATIC TOXICITY (ACUTE) (48-HOUR EC_{50}, 96-HOUR EC_{50}), SECTION 12: Ecological information. **Section 14:** ROAD AND RAIL (ADR/RID), VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, Packing group, ADR - road, IMDG - sea, IATA - air. **Section 15:** COMMENTS. **Section 16:** GENERAL STATEMENTS.
General statements	**:** NAP = Not Applicable NE = Not Established TLV = Threshold Limit Value PEL = Permittable exposure limits MAK = Maximum Workplace Concentration STEL = Short-term exposure limit STEV = Short-term exposure value TWA = Time Weighted Average PPE = Personal Protective Equipment
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.