according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 1/5/2012 **SDS No :** 255-001.2

Date Revised: 12/3/2014

Revision No: 1

PermaShade™ LC Veneer Cement (All Shades)

SECTION 1: Identification of the substance/preparation and of the company/undertaking

1.1. Product identifier

Product code : DD/71102, DE/71103, DF/71104, DG/71105 Product name : PermaShade™ LC Veneer Cement (All Shades)

Product description: Veneer Cement

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

Relevant identified uses: Professional Dental Light Cure Veneer Cement

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

Danger symbols : Xi
R phrases : R36/38

2.2. Label elements

Classification according to Directive 1999/45/EC

Hazard pictogram(s) : X



Irritant

R&S statement(s) : R36/38: Irritating to eyes and skin. Classification according to Regulation (EC) No 1272/2008 [CLP]

Hazard pictogram(s) :



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Signal Word : WARNING

Hazard statement(s): H320: Causes eye irritation.
H315: Causes skin irritation.

2.3. Other hazards

Immediate concerns: No other adverse human effects.

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
Bis GMA	1565-94-2	216-367-7	< 30	Xi; R36/37/38;R22
Triethylene Glycol Dimethacrylate	109-16-0	203-652-6	< 10	Xi; R43

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: Immediately flush eyes with plenty of water. Get medical attention, if

irritation persists.

Following skin: Wash with soap and water.

Following ingestion: If swallowed in small quantity the product is harmless, otherwise

consult a doctor.

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 : Causes eye irritation.

Skin : May cause skin irritation and sensitization.Ingestion : May be harmful if swallowed in large quantities.

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

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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 : 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 : Not Applicable

6.3. Methods and material for containment and cleaning up

Small spill: Wipe up with dry cloth.

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 : Use suitable protective equipment.

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 Dental Light Cure Veneer Cement

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters: Not Determined

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8.2. Exposure controls

Eye/face protection: Wear eye protection

Skin protection : S36/37: 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 : Shade dependent.

Odour : Acrylic

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable : Yes

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

Hazardous polymerization: No

10.4. Conditions to avoid

Conditions to avoid : Heat, flames, ignition sources, direct light, and incompatibles.

10.5. Incompatible materials

Incompatible materials: Not Determined

10.6. Hazardous decomposition products

Hazardous decomposition: None known.

products

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Dermal LD₅₀ : Not Determined
Oral LD₅₀ : Not Determined
Inhalation LC₅₀ : Not Determined

SECTION 12: Ecological information

12.1. Toxicity

Aquatic toxicity (acute)

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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 Established

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)

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

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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: Not Determined

SECTION 16: Other information

Relevant R-phrases and/or Hstatements (number and full

text)

Prepared by

Revision summary

: R22: Harmful if swallowed.

R36/37/38: Irritating to eyes, respiratory system and skin.

R43: May cause sensitization by skin contact.

: Anu Kattoju

: This SDS replaces the 1/5/2012 SDS. Revised: **Section 1**: GENERAL USE, PREPARED BY. **Section 2**: EMERGENCY OVERVIEW -

IMMEDIATE CONCERNS. **Section 4:** INGESTION, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE (

INGESTION, INHALATION, SKIN). Section 5: EXPLOSION HAZARDS,

EXTINGUISHING MEDIA, FIRE EXPLOSION, HAZARDOUS

COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. Section 6: GENERAL PROCEDURES, WATER SPILL, . Section 7: SHELF LIFE, STORAGE, . Section 8: PERSONAL PROTECTIVE EQUIPMENT - RESPIRATORY . Section 9: PERCENT VOLATILE. Section 10: HAZARDOUS DECOMPOSITION PRODUCTS, HAZARDOUS POLYMERIZATION, INCOMPATIBLE

MATERIALS, STABLE. **Section 11:** ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat)). **Section 12:** CHEMICAL FATE

INFORMATION, DISTRIBUTION, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) (48-HOUR EC_{50} , 96-HOUR EC_{50}),

SECTION 12: Ecological information. **Section 14:** AIR (ICAO/IATA) - SPECIAL PROVISIONS ROAD AND RAIL (ADR/RID), ROAD AND RAIL (ADR/RID) (PROPER SHIPPING NAME, UN NUMBER, PACKING GROUP), VESSEL (IMO/IMDG) (SPECIAL PROVISIONS), ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS. **Section 15:** RoHS,

SECTION 15: Regulatory information. **Section 16:** ADDITIONAL

MSDS INFORMATION, GENERAL STATEMENTS.

General statements

Additional SDS information

Manufacturer disclaimer

: NA = Not Applicable

: Revision #:1

: FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material MSDS(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

according to Regulation (EC) No. 453/2010

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