

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 12/15/2006

SDS No : 85-001.6

Date Revised : 04/28/2015

Revision No : 6

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

Product code : PS/63010
Product name : PermaSeal®
Product description : Composite sealer

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

Relevant identified uses : Professional Dental Composite Sealer

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 : R36/37/38,R43

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

Health : Eye Irritation
 Skin Irritation
 Skin Sensitization
 Respiratory Tract Irritation

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

Hazard pictogram(s) : Xi



Irritant

R&S statement(s) : R36/37/38: Irritating to eyes, respiratory system and skin.

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ULTRADENT
 PRODUCTS, INC.

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R43: May cause sensitization by skin contact.

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

Hazard pictogram(s)

:



Exclamation
 mark

Signal Word

: WARNING

Hazard statement(s)

: H315: Causes skin irritation.
 H317: May cause an allergic skin reaction.
 H319: Causes serious eye irritation.
 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.
 P315: Get immediate medical advice/attention.
 P302+P352: IF ON SKIN: Wash with plenty of soap and water.
 P361: Take off immediately all contaminated clothing.
 P333+P313: If skin irritation or rash occurs: Get medical advice/attention.
 P301: IF SWALLOWED:
 P331: Do NOT induce vomiting.
 P304: IF INHALED:
 P313: Get medical advice/attention.

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

: No other adverse human effects.

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

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Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Bis GMA	1565-94-2	216-367-7	60	Xi; R36/37/38; R22	H302; H315; H317; H318; H335; H412
Triethylene Glycol Dimethacrylate	109-16-0	203-652-6	< 40	Xi; R43	H317
2-dimethylaminoethyl Methacrylate	2867-47-2	220-688-8	< 3	T, Xi; R22; R36/37/38; R43	H302; H312; H319; H315; H317

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 for at least 15 minutes. Get immediate medical attention.
- Following skin** : Immediately wash skin with soap and plenty of water. Remove contaminated clothing. Get medical attention if symptoms occur. Wash clothing before reuse.
- Following ingestion** : If swallowed, Do Not Induce Vomiting- Seek Medical Advice.
- Following inhalation** : Remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention.

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

- Eyes** : Contact may cause eye irritation.
- Skin** : May cause skin irritation and sensitization.
- Ingestion** : May be irritating to mouth, throat, and stomach
- Inhalation** : Maybe harmful if inhaled.

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

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PermaSeal®**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** : 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** : Pick up wash liquid with additional absorbent and place in a disposable container.**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** : Store in a cool place in original container and protect from sunlight.**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 Composite Sealer**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. In case of insufficient ventilation, wear suitable respiratory equipment.

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PermaSeal®**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Physical state : Liquid
 Colour : Yellow
 Odour : Acrylic

9.2. Other information

Percent volatile : Not Determined

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

Reactivity : Stable

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 : Heat, flames, ignition sources, direct light, and incompatibles.

10.5. Incompatible materials

Incompatible materials : Not Determined

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****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

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PermaSeal®**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** : 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)****Hazard classification** : N/A**14.4. Packing group****Packing group** : N/A**14.5. Environmental hazards****Marine pollutant #1** : N/A**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**

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Chemical safety assessment : See Section 11

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.
 R43: May cause sensitization by skin contact.
 H302: Harmful if swallowed.
 H312: Harmful in contact with skin.
 H315: Causes skin irritation.
 H317: May cause an allergic skin reaction.
 H318: Causes serious eye damage.
 H319: Causes serious eye irritation.
 H335: May cause respiratory irritation.
 H412: Harmful to aquatic life with long lasting effects.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 07/15/2013 SDS. Revised: **Section 1:** Date-Revised.

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.