SAFETY DATA SHEET
according to Regulation (EC) No. 453/2010
Dental Use

Date Issued : 10/02/2007
SDS No : 68-001.7
Date Revised : 01/17/2017
Revision No : 4

PermaQuick® Bonding Primer

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

1.1. Product identifier

Product code : PQ/ 63302
Product name : PermaQuick® Bonding Primer
Product description : Dentin and enamel bonding primer

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

Relevant identified uses : Professional Dental Priming Agent

1.3. Details of the supplier of the safety data sheet

Manufacturer
Ultradent Products, Inc.
505 W. Ultradent Drive (10200 South)
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 Regulation(EC) No 1272/2008 [CLP]

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

Health
: Eye Irritation, Category 2B
Skin Irritation, Category 2
Skin Sensitization, Category 1B

Environmental
: Chronic Hazards to the Aquatic Environment, Category 2

Physical
: Flammable Liquids, Category 2

2.2. Label elements

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

Hazard pictogram(s) : ![Exclamation mark](image) ![Flame](image)

Signal Word : DANGER

Hazard statement(s) : H225: Highly flammable liquid and vapour.
H315: Causes skin irritation.
H317: May cause an allergic skin reaction.
PermaQuick® Bonding Primer

H319: Causes serious eye irritation.
H411: Toxic to aquatic life with long lasting effects.

Precautionary statement(s)

P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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.
P333+P313: If skin irritation or rash occurs: Get medical advice/attention.

Storage : P273: Avoid release to the environment.


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

<table>
<thead>
<tr>
<th>Chemical Name</th>
<th>CAS</th>
<th>EINECS No.</th>
<th>Wt.%</th>
<th>Classification according to Regulation(EC) No 1272/2008 [CLP]</th>
</tr>
</thead>
<tbody>
<tr>
<td>2-hydroxyethyl Methacrylate</td>
<td>868-77-9</td>
<td>212-782-2</td>
<td>&lt; 50</td>
<td>Eye Irr.,Cat. 2B; Skin Sens.,Cat. 1B; H317; H319</td>
</tr>
<tr>
<td>Canada balsam</td>
<td>8007-47-4</td>
<td>232-362-2</td>
<td>&lt; 25</td>
<td>Skin Sens.,Cat. 1; Aquatic Chronic,Cat. 2; H317; H411</td>
</tr>
<tr>
<td>Ethyl Alcohol</td>
<td>64-17-5</td>
<td>200-578-6</td>
<td>≤ 20</td>
<td>Flam. Liq.,Cat. 2; Eye Irr.,Cat. 2; Skin Irr.,Cat. 2; STOT SE,Cat. 3; H225; H319</td>
</tr>
<tr>
<td>Methacrylic Acid</td>
<td>79-41-4</td>
<td>201-204-4</td>
<td>&lt; 10</td>
<td>Skin Corr.,Cat. 1A; Acute Tox. (O),Cat. 4; Acute Tox. (D),Cat. 4; H302; H312; H227</td>
</tr>
<tr>
<td>Camphorquinone</td>
<td>10373-78-1</td>
<td>233-814-1</td>
<td>≤ 1</td>
<td>Skin Irr., Cat. 2; Eye Irr., Cat. 2; STOT SE, Cat. 3; H315; H319; H335</td>
</tr>
</tbody>
</table>

For full text of H-statements: 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. Get medical attention if irritation develops or persists.
PermaQuick® Bonding Primer

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.

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

Eyes : Irritating to eyes.

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

5.1. Extinguishing media

Extinguishing media : Foam, dry chemical, carbon dioxide (CO₂).

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 : Absorb with inert, damp non-combustible material, then flush area with water.

6.4. Reference to other sections

Reference to other sections : Not Applicable

SECTION 7: Handling and storage

7.1. Precautions for safe handling

General procedures : Avoid contact with eyes, skin and clothing.

Handling : Follow all SDS/label precautions even after container is emptied because they may retain product residues.
PermaQuick® Bonding Primer

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 Priming Agent

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters: Ethyl Alcohol CAS: 64-17-5

<table>
<thead>
<tr>
<th>Control Parameters</th>
<th>Exposure Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>OSHA PEL General Industry</td>
<td>1000 ppm (1900 mg/m3)</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
</tr>
<tr>
<td>OSHA PEL - Construction Industry</td>
<td>1000 ppm (900 mg/m3)</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
</tr>
<tr>
<td>OSHA PEL Shipyard Employment</td>
<td>1000 ppm (1900 mg/m3)</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
</tr>
<tr>
<td>NIOSH REL</td>
<td>1000 ppm (1900 mg/m3)</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
</tr>
<tr>
<td>ACGIH TLV</td>
<td>1000 ppm (1880 mg/m3)</td>
</tr>
<tr>
<td></td>
<td>STEL</td>
</tr>
<tr>
<td>CAL/OSHA PEL</td>
<td>1000 ppm (1900 mg/m3)</td>
</tr>
<tr>
<td></td>
<td>TWA</td>
</tr>
</tbody>
</table>

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: Liquid

Appearance: Clear, low viscosity liquid

Colour: Yellow

Odour: Conifer

pH: NAP (non-aqueous)

Specific gravity: 0.8 to 1.1

9.2. Other information

Additional information: No further relevant information available.
## 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.

### 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
- **Dermal LD$_{50}$** : > 2000 mg/kg Rabbit/Rat
  - **Notes** : ~44% of the mixture consists of components of unknown toxicity (Dermal).
- **Oral LD$_{50}$** : > 3200 mg/kg Rat/Guinea Pig/Mouse
  - **Notes** : 23% of the mixture consists of components of unknown toxicity (Oral).
- **Inhalation LC$_{50}$** : > 34 mg/L/4H Rat
  - **Notes** : ~71% 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.
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12.6. Other adverse effects

Environmental data: Do not flush to sewer.

SECTION 13: Disposal considerations

13.1. Waste treatment methods


SECTION 14: Transport information

14.1. UN number

UN number: 1987

14.2. UN proper shipping name

UN proper shipping name: Alcohols, n.o.s. (Ethyl alcohol mixture)

14.3. Transport hazard class(es)

Primary hazard class/division: 3
Hazard classification: 3

14.4. Packing group

Packing group: III

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: Substances of very high concern (SVHC) according to REACH, Article 57: Contains no SVHC substances.

General comments: Please refer to Medical Devices Directive 93/42/EEC.

15.2. Chemical safety assessment

Chemical safety assessment: See Section 11
Additional information: None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop 65.
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Relevant H-statements (number and full text):
- Acute Tox. (D), Cat. 4: Acute Toxicity (Dermal), Category 4
- Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4
- Aquatic Chronic, Cat. 2: Chronic Hazards to the Aquatic Environment, Category 2
- Eye Irr., Cat. 2B: Eye Irritation, Category 2B
- Eye Irr., Cat. 2: Eye Irritation, Category 2
- Flam. Liq., Cat. 2: Flammable Liquids, Category 2
- STOT SE, Cat 3: Target Organ Toxicity (Single exposure), Category 3
- STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Respiratory Tract Category 3
- Skin Corr., Cat. 1A: Skin Corrosion, Category 1A
- Skin Irr., Cat. 2: Skin Irritation, Category 2
- Skin Sens., Cat. 1B: Skin Sensitization, Category 1B
- Skin Sens., Cat. 1: Skin Sensitization, Category 1
- H225: Highly flammable liquid and vapour.
- H227: Combustible liquid.
- 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.
- H335: May cause respiratory irritation.
- H411: Toxic to aquatic life with long lasting effects.

Prepared by: Anu Kattoju
Revision summary: This SDS replaces the 07/21/2015 SDS. Revised:
- Section 1: MSDS No.
- Section 2: EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3.
- Other hazards.
- Section 3: Wt. %.
- Section 4: INHALATION.
- Section 5: EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT.
- Section 7: GENERAL PROCEDURES.
- Section 8: . Section 9: APPEARANCE, COMMENTS, ODOR, PERCENT VOLATILE, pH, PHYSICAL STATE, SPECIFIC GRAVITY.
- Section 11: ACUTE (DERMAL LD<sub>50</sub> (rabbit), DERMAL LD<sub>50</sub> (rabbit), DERMAL LD<sub>50</sub> (rabbit), ORAL LD<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat) ACUTE, GENERAL COMMENTS.
- Section 12: CHEMICAL FATE INFORMATION, DISTRIBUTION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) (48-HOUR EC<sub>50</sub>, 96-HOUR EC<sub>50</sub> ), SECTION 12: Ecological information.
- Section 14: VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, ADR - road, IMDG - sea, IATA - air.
- Section 15: COMMENTS, GENERAL COMMENTS, RoHS.
- Section 16: GENERAL STATEMENTS.

General statements:
- NAP = Not Applicable
- NE = Not Established
- TLV = Threshold Limit Value
- PEL = Permittable exposure limits
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MAK = Maximum Workplace Concentration
STEL = Short-term exposure limit
STEV = Short-term exposure value
TWA = Time Weighted Average
PPE = Personal Protective Equipment
AMU = Atomic Mass Unit

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.