

# SAFETY DATA SHEET

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



Date Issued : 02/23/2006  
SDS No : 26-001.10  
Date Revised : 07/18/2016  
Revision No : 10

PQ1™

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

### 1.1. Product identifier

Product code : PO/63311  
Product name : PQ1™  
Product description : Single resin bonding agent

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

Relevant identified uses : Professional Dental Bonding Agent

### 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 : F,Xi

R phrases : R36,R22

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

Health : Acute Toxicity (Inhalation), Category 4  
Eye Irritation, Category 2B  
Skin Irritation, Category 2  
Skin Sensitization, Category 1B

Physical : Flammable Liquids, Category 2

### 2.2. Label elements

#### Classification according to Directive 1999/45/EC

Hazard pictogram(s) : F Xi



Highly  
flammable



Irritant

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## PQ1™

|                                                                      |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
|----------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| <b>R&amp; statement(s)</b>                                           | : R36: Irritating to eyes.<br>R22: Harmful if swallowed.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Classification according to Regulation(EC) No 1272/2008 [CLP]</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Hazard pictogram(s)</b>                                           | :  <br>Exclamation mark      Flame                                                                                                                                                                                                                                                                                                                                                   |
| <b>Signal Word</b>                                                   | : DANGER                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| <b>Hazard statement(s)</b>                                           | : H225: Highly flammable liquid and vapour.<br>H319: Causes serious eye irritation.<br>H315: Causes skin irritation.<br>H317: May cause an allergic skin reaction.<br>H335: May cause respiratory irritation.                                                                                                                                                                                                                                                                                                                                          |
| <b>Precautionary statement(s)</b>                                    |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| <b>Prevention</b>                                                    | : P280: Wear protective gloves/protective clothing/eye protection/face protection.<br>P210: Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.                                                                                                                                                                                                                                                                                                                                                             |
| <b>Response</b>                                                      | : P305: IF IN EYES:<br>P351: Rinse cautiously with water for several minutes.<br>P337+P313: If eye irritation persists: Get medical advice/attention.<br>P302+P352: IF ON SKIN: Wash with plenty of soap and water.<br>P333+P313: If skin irritation or rash occurs: Get medical advice/attention.<br>P301: IF SWALLOWED:<br>P311: Call a POISON CENTER or doctor/physician.<br>P330: Rinse mouth.<br>P331: Do NOT induce vomiting.<br>P304: IF INHALED:<br>P342+P311: If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician. |
| <b>Storage</b>                                                       | : P273: Avoid release to the environment.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| <b>Disposal</b>                                                      | : 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

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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]                      |
|-----------------------------|-----------|------------|------|--------------------------------------------------|------------------------------------------------------------------------------------|
| Ethyl Alcohol               | 64-17-5   | 200-578-6  | < 10 | F; R11                                           | Flam. Liq.,Cat. 2; Eye Irr.,Cat. 2; Skin Irr.,Cat. 2; STOT SE,Cat. 3; H225; H319   |
| 2-hydroxyethyl Methacrylate | 868-77-9  | 212-782-2  | < 15 | Xi; R43; R36/38                                  | Eye Irr.,Cat. 2B; Skin Sens.,Cat. 1B; H317; H319                                   |
| Methacrylic Acid            | 79-41-4   | 201-204-4  | < 10 | C; R34                                           | Skin Corr.,Cat. 1A; Acute Tox. (O),Cat. 4; Acute Tox. (D),Cat. 4; H302; H312; H227 |
| Bis-GMA                     | 1565-94-2 | 216-367-7  | ≤ 10 | Xi; R22; R36/37/38                               | Skin Irr.,Cat. 2; Eye Irr.,Cat. 2B; Skin Sens.,Cat. 1                              |

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. Get medical attention if irritation develops or persists.
- Following ingestion** : If swallowed, rinse mouth with water, Do NOT Induce Vomiting. Give victim a glass of water or milk. Call a physician or poison control center if you feel unwell.
- Following inhalation** : If inhaled, remove to fresh air. If not breathing give artificial respiration. If breathing is difficult, give oxygen.

#### 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.
- 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** : Foam, dry chemical, carbon dioxide (CO<sub>2</sub>).

#### 5.2. Special hazards arising from the substance or mixture

- Hazardous combustion products** : Not Available

#### 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.

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## 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** : Absorb liquid and place in sealed container for disposal. Vapors can travel to an ignition source.

**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

**Handling** : Keep away from heat, sparks and flame.

**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 Bonding Agent

## SECTION 8: Exposure controls / personal protection

### 8.1. Control parameters

**Control parameters** : HEMA CAS: 868-77-9

| Control Parameters | Exposure Limits                     |
|--------------------|-------------------------------------|
| TLV                | Not Established                     |
| MAK                | Sensitization of skin(Sh); DFG 2008 |

Methacrylic Acid CAS: 79-41-4

| Control Parameters | Exposure Limits             |
|--------------------|-----------------------------|
| NIOSH REL          | TWA 20 ppm(70 mg/m3) [skin] |
| OSHA PEL           | none                        |
| ACGIH TLV          | 20 ppm; 70 mg/m3 TWA        |

Aluminum Oxide (Respirable Fraction & Total Dust) CAS: 1344-28-1

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| Control Parameters        | Exposure Limits                     |
|---------------------------|-------------------------------------|
| OSHA PEL General Industry | 5mg/m3                              |
| OSHA PEL Maritime         | 5 mg/m3                             |
| ACGIH TLV                 | 1 mg/m3 TWA; Respirable fraction    |
| NIOSH REL                 | Substances With No Established RELs |

Ethyl Alcohol CAS: 64-17-5

| Control Parameters               | Exposure Limits           |
|----------------------------------|---------------------------|
| OSHA PEL General Industry        | 1000 ppm (1900 mg/m3) TWA |
| OSHA PEL - Construction Industry | 1000 ppm (1900 mg/m3) TWA |
| OSHA PEL Shipyard Employment     | 1000 ppm(1900 mg/m3) TWA  |
| NIOSH REL                        | 1000 ppm(1900 mg/m3) TWA  |
| ACGIH TLV                        | 1000 ppm(1880 mg/m3) STEL |
| CAL/OSHA PEL                     | 1000 ppm(1900 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** : Liquid, medium viscosity

**Appearance** : Yellow resin

**Colour** : Yellow

**Odour** : Acrylic, pungent

### 9.2. Other information

**Percent volatile** : Not Determined

## SECTION 10: Stability and reactivity

### 10.1. Reactivity

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**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 and sparks. Extremes of temperature and direct sunlight.

## 10.5. Incompatible materials

**Incompatible materials** : None known.

## 10.6. Hazardous decomposition products

**Hazardous decomposition products** : None known.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

#### Acute

**Dermal LD<sub>50</sub>** : > 2500 mg/kg rat/rabbit

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

**Oral LD<sub>50</sub>** : > 4500 mg/kg rat/guinea pig

**Notes** : ~44% of the mixture consists of components of unknown toxicity (oral)

**Inhalation LC<sub>50</sub>** : > 11.0 mg/L/4H mouse/rat

**Notes** : 55% 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** : Harmful to aquatic life with long lasting effects.

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## 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** : 1987

### 14.2. UN proper shipping name

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

### 14.3. Transport hazard class(es)

**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 comments** : 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)** : R11: Highly flammable.  
R22: Harmful if swallowed.  
R34: Causes burns.  
R36/37/38: Irritating to eyes, respiratory system and skin.  
R36/38: Irritating to eyes and skin.  
R43: May cause sensitization by skin contact.  
Acute Tox. (D), Cat. 4: Acute Toxicity (Dermal), Category 4  
Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4  
Eye Irr., Cat. 2B: Eye Irritation, Category 2B

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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  
 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.  
 H317: May cause an allergic skin reaction.  
 H319: Causes serious eye irritation.

## Prepared by

: Anu Kattoju

## Revision summary

: This SDS replaces the 04/10/2015 SDS. Revised: **Section 1:** MSDS No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 4:** INHALATION, SIGNS AND SYMPTOMS OF OVEREXPOSURE - INHALATION. **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 8:** . **Section 10:** CONDITIONS TO AVOID. **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), INHALATION LC<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:** GENERAL COMMENTS, RoHS. **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.

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Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.