

SAFETY DATA SHEET

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

ULTRADENT
PRODUCTS, INC.

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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R& statement(s) : R36: Irritating to eyes.
R22: Harmful if swallowed.

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

Hazard pictogram(s) :  
Exclamation mark Flame

Signal Word : DANGER

Hazard statement(s) : H225: Highly flammable liquid and vapour.
H319: Causes serious eye irritation.
H315: Causes skin irritation.
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.
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.
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.
P301: IF SWALLOWED:
P311: Call a POISON CENTER or doctor/physician.
P330: Rinse mouth.
P331: Do NOT induce vomiting.
P304: IF INHALED:
P342+P311: If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

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

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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 (CO₂).

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/m ³
OSHA PEL Maritime	5 mg/m ³
ACGIH TLV	1 mg/m ³ 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/m ³) TWA
OSHA PEL - Construction Industry	1000 ppm (1900 mg/m ³) TWA
OSHA PEL Shipyard Employment	1000 ppm(1900 mg/m ³) TWA
NIOSH REL	1000 ppm(1900 mg/m ³) TWA
ACGIH TLV	1000 ppm(1880 mg/m ³) STEL
CAL/OSHA PEL	1000 ppm(1900 mg/m ³) 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 LD₅₀ : > 2500 mg/kg rat/rabbit

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

Oral LD₅₀ : > 4500 mg/kg rat/guinea pig

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

Inhalation LC₅₀ : > 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 LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat) ACUTE, GENERAL COMMENTS. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), 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.