

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 12/13/2006

SDS No : 80-001.6

Date Revised : 04/10/2017

Revision No : 6

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

Product code : PK/63400
 Product name : PermaQuick® Bond Resin
 Product description : Dental bonding resin

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

Relevant identified uses : Professional Dental Bonding Resin

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 : Skin Irritation, Category 2
 Eye Irritation, Category 2
 Skin Sensitization, Category 1
 Target Organ Toxicity (Single exposure), Category 3

2.2. Label elements**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.

SAFETY DATA SHEET

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



Date Issued : 12/13/2006
SDS No : 80-001.6
Date Revised : 04/10/2017
Revision No : 6

PermaQuick® Bond Resin

Precautionary statement(s)

- Prevention** : P280: Wear protective gloves/protective clothing/eye protection/face protection.
P264: Wash hands thoroughly after handling.
P261: Avoid breathing dust/fumes/gas/mist/vapours/spray.
P272: Contaminated work clothing should not be allowed out of the workplace.
P312: Call a POISON CENTER or doctor/physician if you feel unwell.
P271: Use only outdoors or in a well-ventilated area.
- Response** : P305: IF IN EYES:
P351: Rinse cautiously with water for several minutes.
P338: Remove contact lenses, if present and easy to do. Continue rinsing.
P337+P313: If eye irritation persists: Get 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.
P363: Wash contaminated clothing before reuse.
P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P304+P312: IF INHALED: Call a POISON CENTER or doctor/physician if you feel unwell.
- Storage** : P273: Avoid release to the environment.
P403+P233: Store in a well-ventilated place. Keep container tightly closed.
P405: Store locked up.
- Disposal** : P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-21/11/2003)

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

Chemical Name	CAS	EINECS No.	Wt.%	Classification according to Regulation(EC) No 1272/2008 [CLP]
Bis-GMA	1565-94-2	216-367-7	< 20	H315; H317; H319
2-hydroxyethyl Methacrylate	868-77-9	212-782-2	< 20	Eye Irr.,Cat. 2B; Skin Sens.,Cat. 1B; H317; H319
2-dimethylaminoethyl Methacrylate	2867-47-2	220-688-8	< 5	Acute Tox. (O),Cat. 4; Skin Corr.,Cat. 1C; Flam. Liq.,Cat. 4; H302; H314; H227
Barium aluminosilicate glass powder	65997-17-3	NAP	< 45	Skin Irr.,Cat. 2; Eye Irr.,Cat. 2B; STOT SE,Cat 3; H315; H319; H335

For full text of H-statements: see SECTION 16.

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



Date Issued : 12/13/2006
SDS No : 80-001.6
Date Revised : 04/10/2017
Revision No : 6

PermaQuick® Bond Resin

SECTION 4: First aid measures

4.1. Description of first aid measures

- Following eyes** : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical advice/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 rinse mouth out with water. Seek medical attention if you feel unwell.
- Following inhalation** : Remove to open air. In the event of breathing difficulties get medical advice/attention immediately.

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** : May be harmful if inhaled.

4.3. Indication of any immediate medical attention and special treatment needed

- Notes to physician** : NAP

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** : 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** : NAP

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



Date Issued : 12/13/2006
 SDS No : 80-001.6
 Date Revised : 04/10/2017
 Revision No : 6

PermaQuick® Bond Resin

SECTION 7: Handling and storage

7.1. Precautions for safe handling

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

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : None Required

8.2. Exposure controls

Eye/face protection : Wear eye protection .
Skin protection : Wear suitable protective clothing and gloves.
Respiratory protection : Use only in well-ventilated areas.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Medium viscosity solution
Appearance : Opaque
Colour : Pale Yellow
Odour : Acrylic
pH : NAP (non-aqueous)
Specific gravity : 1.5 - 1.6

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

SAFETY DATA SHEET

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



Date Issued : 12/13/2006
SDS No : 80-001.6
Date Revised : 04/10/2017
Revision No : 6

PermaQuick® Bond Resin

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 LD₅₀ : > 3000 mg/kg Rabbit/Rat

Notes : ~80% of the mixture consists of components of unknown toxicity (Dermal)

Oral LD₅₀ : > 3200 mg/kg Rat

Notes : ~75% of the mixture consists of components of unknown toxicity (Oral)

Inhalation LC₅₀ : > 7 mg/L/4H Rat/Guinea Pig Dust/Mist

Notes : ~84% of the mixture consists of components of unknown toxicity (Inhalation).
This substance is a viscous gel, therefore, chance of inhalation is extremely low.

Germ cell mutagenicity : The components in this product are not reported to produce mutagenic effects in humans.

Carcinogenicity : None of the components of this material are listed by IARC, NTP, or CA Prop 65 as carcinogens.

Reproductive toxicity : The components in this product are not reported to cause reproductive effects in humans.

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 : No further relevant information available.

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



Date Issued : 12/13/2006
 SDS No : 80-001.6
 Date Revised : 04/10/2017
 Revision No : 6

PermaQuick® Bond Resin

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 : NAP

14.2. UN proper shipping name

UN proper shipping name : Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification : NAP

14.4. Packing group

Packing group : NAP

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.
 This product is not considered dangerous for transportation.

SECTION 16: Other information

Relevant H-statements (number and full text) : Acute Tox. (O), Cat. 4: Acute Toxicity (Oral), Category 4
 Eye Irr., Cat. 2B: Eye Irritation, Category 2B
 Flam. Liq., Cat. 4: Flammable Liquids, Category 4

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 12/13/2006

SDS No : 80-001.6

Date Revised : 04/10/2017

Revision No : 6

PermaQuick® Bond Resin

STOT SE, Cat 3: Target Organ Toxicity (Single exposure), Category 3

Skin Corr., Cat. 1C: Skin Corrosion, Category 1C

Skin Irr., Cat. 2: Skin Irritation, Category 2

Skin Sens., Cat. 1B: Skin Sensitization, Category 1B

H227: Combustible liquid.

H302: Harmful if swallowed.

H314: Causes severe skin burns and eye damage.

H315: Causes skin irritation.

H317: May cause an allergic skin reaction.

H319: Causes serious eye irritation.

H335: May cause respiratory irritation.

Prepared by

: Anu Kattoju

Revision summary

: This SDS replaces the 06/08/2015 SDS. Revised: **Section 1:** MSDS No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 4:** EYES, INGESTION, INHALATION, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE (INHALATION). **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** . **Section 7:** GENERAL PROCEDURES. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - RESPIRATORY . **Section 9:** APPEARANCE, COLOR, COMMENTS, PERCENT VOLATILE, pH, PHYSICAL STATE, SPECIFIC GRAVITY. **Section 10:** HAZARDOUS POLYMERIZATION. **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, CARCINOGENICITY, GERM CELL MUTAGENICITY, REPRODUCTIVE TOXICITY. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), SECTION 12: Ecological information. **Section 14:** ROAD AND RAIL (ADR/RID), VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, UN number, Packing group, 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
 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

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



Date Issued : 12/13/2006
SDS No : 80-001.6
Date Revised : 04/10/2017
Revision No : 6

PermaQuick® Bond Resin

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.