Safety data sheet
described, according to Annex XVII of 1907/2006/EC, Article 31

1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** PQ1™
- **Article number:** 63311
- **Index number:** SDS 26-001.11
- **Relevant identified uses of the substance or mixture and uses advised against**
  - **Professional Dental Bonding Agent**
- **Application of the substance / the mixture** Professional Dental Bonding Agent

2. **Hazards identification**

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**

  - **GHS02** flame
  - Flam. Liq. 3 H226 Flammable liquid and vapour.

  - **GHS05** corrosion
  - Skin Corr. 1A H314 Causes severe skin burns and eye damage.
  - Eye Dam. 1 H318 Causes serious eye damage.

  - **GHS07**
  - Skin Sens. 1 H317 May cause an allergic skin reaction.
  - STOT SE 3 H335 May cause respiratory irritation.

(Contd. on page 2)
Trade name: PQ1™

- Label elements
- Labelling according to Regulation (EC) No 1272/2008
  The Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (CLP) shall not apply to a medical device in the finished state used in direct physical contact with the human body according to Art. 1.5 (d). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6c), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.
- Hazard pictograms GHS02, GHS05, GHS07
- Signal word Danger

- Hazard-determining components of labelling:
  Trade Secret
  2-Hydroxyethyl Methacrylate
  Methacrylic Acid
  Organophosphine Oxide
- Hazard statements
  H226 Flammable liquid and vapour.
  H314 Causes severe skin burns and eye damage.
  H317 May cause an allergic skin reaction.
  H335 May cause respiratory irritation.
- Precautionary statements
  P101 If medical advice is needed, have product container or label at hand.
  P102 Keep out of reach of children.
  P103 Read label before use.
  P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water/shower.
  P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  P310 Immediately call a POISON CENTER/doctor.
  P321 Specific treatment (see on this label).
  P362+P364 Take off contaminated clothing and wash it before reuse.
  P405 Store locked up.
  P501 Dispose of contents/container in accordance with local/regional/national/international regulations.
- Other hazards
- Results of PBT and vPvB assessment
  - PBT: Not applicable.
  - vPvB: Not applicable.

3 Composition/information on ingredients

- Chemical characterisation: Mixtures
- Description: Mixture of substances listed below with nonhazardous additions.

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>2-Hydroxyethyl Methacrylate</td>
<td>2-Hydroxyethyl Methacrylate</td>
<td>Skin Irrit. 2, H315; Eye Irrit. 2, H319; Skin Sens. 1, H317</td>
<td>Ethyl Alcohol</td>
<td>Flam. Liq. 2, H225</td>
<td>Methacrylic Acid</td>
<td>Acute Tox. 3, H331; Skin Corr. 1A, H314; Eye Dam. 1, H318; Acute Tox. 4, H302; Acute Tox. 4, H312</td>
<td></td>
</tr>
<tr>
<td>2-Hydroxyethyl Methacrylate</td>
<td>Skin Corr. 1A, H314; Eye Dam. 1, H318</td>
<td>Skin Corr. 1A, H314; Eye Dam. 1, H318; Skin Corr. 1A, H314; Eye Dam. 1, H318; Skin Corr. 1A, H314; Eye Dam. 1, H318; Skin Corr. 1A, H314; Eye Dam. 1, H318</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>&lt;25%</td>
<td>&lt;15%</td>
<td>&lt;10%</td>
<td>&lt;6%</td>
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</tbody>
</table>
4 First aid measures

· **General information:** Immediately remove any clothing soiled by the product.

· **After inhalation:**
  Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

· **After skin contact:**
  Immediately wash with water and soap and rinse thoroughly.

· **After eye contact:**
  Rinse opened eye for several minutes under running water. Then consult a doctor.

· **After swallowing:**
  Rinse mouth with water.
  Do not induce vomiting; call for medical help immediately.

· **Information for doctor:**
  No further relevant information available.

5 Firefighting measures

· **Extinguishing media**

· **Suitable extinguishing agents:** Foam, dry chemical, carbon dioxide

· **For safety reasons unsuitable extinguishing agents:** Water with full jet

· **Special hazards arising from the substance or mixture**
  During heating or in case of fire poisonous gases are produced.

· **Advice for firefighters:**

· **Protective equipment:**
  Wear fully protective suit.
  Mouth respiratory protective device.

6 Accidental release measures

· **Personal precautions, protective equipment and emergency procedures**
  Mount respiratory protective device.
  Wear protective equipment. Keep unprotected persons away.

· **Environmental precautions:** Do not allow to enter sewers/surface or ground water.

· **Methods and material for containment and cleaning up:**
  Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
  Dispose contaminated material as waste according to item 13.
  Ensure adequate ventilation.

· **Reference to other sections**
  See Section 7 for information on safe handling.
  See Section 8 for information on personal protection equipment.
  See Section 13 for disposal information.
7 Handling and storage

- Handling:
  - Precautions for safe handling:
    Ensure good ventilation/exhaustion at the workplace.
    Prevent formation of aerosols.
  - Information about fire - and explosion protection:
    Keep ignition sources away - Do not smoke.
    Keep respiratory protective device available.
- Conditions for safe storage, including any incompatibilities
  - Storage:
    - Requirements to be met by storerooms and receptacles: Store in a cool location.
    - Information about storage in one common storage facility: Not required.
    - Further information about storage conditions:
      See product labelling.
      Keep container tightly sealed.
- Specific end use(s) Professional Dental Bonding Agent

8 Exposure controls/personal protection

- Additional information about design of technical facilities: No further data; see item 7.
- Control parameters
  - Ingredients with limit values that require monitoring at the workplace:
    | CAS Number | Substance                      | WEL (Great Britain)                                                                 |
    |------------|--------------------------------|-------------------------------------------------------------------------------------|
    | 64-17-5    | Ethyl Alcohol                  | Long-term value: 1920 mg/m³, 1000 ppm                                              |
    | 79-41-4    | Methacrylic Acid               | Short-term value: 143 mg/m³, 40 ppm                                                 |
    |            |                                | Long-term value: 72 mg/m³, 20 ppm                                                  |
    | 128-37-0   | Butylated Hydroxytoluene       | WEL (Great Britain)                                                                 |
    |            |                                | Long-term value: 10 mg/m³                                                           |
  - Additional information: The lists valid during the making were used as basis.
- Exposure controls
- Personal protective equipment:
  - General protective and hygienic measures:
    Ensure that washing facilities are available at the work place.
    Keep away from foodstuffs, beverages and feed.
    Immediately remove all soiled and contaminated clothing.
    Wash hands before breaks and at the end of work.
    Avoid contact with the eyes.
    Avoid contact with the eyes and skin.
  - Respiratory protection:
    In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.
- Protection of hands:

Protective gloves
Trade name: PQ1™

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture.

Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

· Material of gloves
  The selection of suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked prior to the application.

· Penetration time of glove material
  The exact breakthrough time has to be found out by the manufacturer of the protective gloves and has to be observed.

· Eye protection:
  Tightly sealed goggles

· Body protection: Protective work clothing

9 Physical and chemical properties

· Information on basic physical and chemical properties
  · General Information
    · Appearance:
      Form: Liquid
      Colour: Yellow
      Odour: Acrylic
      Pungent
    · Odour threshold: Not determined.
  · pH-value:
    Not applicable (non-aqueous)
  · Change in condition
    Melting point/freezing point: Undetermined.
    Initial boiling point and boiling range: Undetermined.
  · Flash point:
    36 °C
  · Flammability (solid, gas):
    Not applicable.
  · Decomposition temperature:
    Not determined.
  · Auto-ignition temperature:
    Product is not selfigniting.
  · Explosive properties:
    Product is not explosive. However, formation of explosive air/vapour mixtures are possible.
  · Explosion limits:
    Lower: Not determined.
    Upper: Not determined.
  · Vapour pressure:
    Not determined.
  · Density at 20 °C:
    1.39 g/cm³
  · Relative density:
    Not determined.
  · Vapour density:
    Not determined.
  · Evaporation rate:
    Not determined.
49.4.3.1 · Solubility in / Miscibility with water: Not miscible or difficult to mix.

· Partition coefficient: n-octanol/water: Not determined.

· Viscosity:
  Dynamic: Not determined.
  Kinematic: Not determined.

· Solvent content:
  VOC (EC) 0.00 %

· Other information No further relevant information available.

10 Stability and reactivity

· Reactivity Stable
· Chemical stability Stable under recommended conditions.
· Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
· Possibility of hazardous reactions: No dangerous reactions known.
· Conditions to avoid:
  Light
  Sparks
  Flames
  Heat
· Incompatible materials: No further relevant information available.
· Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

· Information on toxicological effects
· Acute toxicity Based on available data, the classification criteria are not met.

· LD/LC50 values relevant for classification:

  ATE (Acute Toxicity Estimates)
<table>
<thead>
<tr>
<th>Route</th>
<th>LD50</th>
<th>LC50/4 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>LD50</td>
<td>17,667 mg/kg</td>
</tr>
<tr>
<td>Dermal</td>
<td>LD50</td>
<td>8,333 mg/kg (rabbit)</td>
</tr>
<tr>
<td>Inhalative</td>
<td>LC50/4 h</td>
<td>118 mg/l</td>
</tr>
</tbody>
</table>

  868-77-9 2-Hydroxyethyl Methacrylate
<table>
<thead>
<tr>
<th>Route</th>
<th>LD50</th>
<th>LC50</th>
<th>LC50 Fish</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>LD50</td>
<td>3,275 mg/kg (mouse)</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>&gt;5,000 mg/kg (rat)</td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td>LC50 Fish</td>
<td>&gt;100 mg/l (Fish)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LD50</td>
<td>&gt;3,000 mg/kg (rabbit)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>LC50 (Daphnia magna)</td>
<td>24.1 mg/l (daphnia)</td>
<td></td>
</tr>
</tbody>
</table>

  64-17-5 Ethyl Alcohol
<table>
<thead>
<tr>
<th>Route</th>
<th>LD50</th>
<th>LC50 Fish</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>LD50</td>
<td>5,600 mg/kg (Guinea pig)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3,400 mg/kg (mouse)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>7,060 mg/kg (rat)</td>
</tr>
<tr>
<td></td>
<td>LC50 Fish</td>
<td>&gt;10,000 mg/l (Fish)</td>
</tr>
</tbody>
</table>
### 4.3.1 Inhalative LC50/4 h

- **39 mg/l (mouse)**
- **20,000 mg/l (rat)**

#### 79-41-4 Methacrylic Acid

<table>
<thead>
<tr>
<th>Route</th>
<th>LC50</th>
<th>LD50</th>
<th>LD50 Fish</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td></td>
<td>1,250 mg/kg (mouse)</td>
<td>1,060 mg/kg (rat)</td>
</tr>
<tr>
<td>Dermal</td>
<td>LC50 Fish</td>
<td>86 mg/l (Fish)</td>
<td>1,200 mg/kg (rabbit)</td>
</tr>
<tr>
<td>Inhalative</td>
<td>LC50/4 h</td>
<td>1,000 mg/kg (Guinea pig)</td>
<td>500 mg/kg (rabbit)</td>
</tr>
</tbody>
</table>

#### 162881-26-7 Organophosphine Oxide

<table>
<thead>
<tr>
<th>Route</th>
<th>LD50</th>
<th>LD50 Fish</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>&gt;2,000 mg/kg (rat)</td>
<td>&gt;0.09 mg/l (Fish) (Toxicity to fish)</td>
</tr>
<tr>
<td>Dermal</td>
<td>LD50</td>
<td>&gt;2,000 mg/kg (rat)</td>
</tr>
</tbody>
</table>

#### 128-37-0 Butylated Hydroxytoluene

<table>
<thead>
<tr>
<th>Route</th>
<th>LD50</th>
<th>LD50 Fish</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>10,700 mg/kg (Guinea pig)</td>
<td>1,040 mg/kg (mouse)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>890 mg/kg (rat)</td>
</tr>
<tr>
<td>Dermal</td>
<td>LC50 Fish</td>
<td>5.3 mg/l (Fish)</td>
</tr>
<tr>
<td></td>
<td>LD50</td>
<td>&gt;2,000 mg/kg (rat)</td>
</tr>
</tbody>
</table>

#### Primary irritant effect:

- **Skin corrosion/irritation**
  - Causes severe skin burns and eye damage.
- **Serious eye damage/irritation**
  - Causes serious eye damage.
- **Respiratory or skin sensitisation**
  - May cause an allergic skin reaction.
- **CMR effects (carcinogenity, mutagenicity and toxicity for reproduction)**
  - **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
  - **Carcinogenicity** Based on available data, the classification criteria are not met.
  - **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure**
  - May cause respiratory irritation.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

### 12 Ecological information

#### Toxicity

- **Aquatic toxicity:**
  - **868-77-9 2-Hydroxyethyl Methacrylate**
    - EC50 | 345 mg/l (Algae) |
  - **64-17-5 Ethyl Alcohol**
    - **Algae Toxicity** | 1,000 mg/l (Algae) |
  - **79-41-4 Methacrylic Acid**
    - EC50 | <180 mg/kg (daphnia) (Toxicity to aquatic invertebrates) |
49.4.3.1  
EC50 45 mg/l (Algae) (Toxicity to algae)  
162881-26-7 Organophosphine Oxide  
<table>
<thead>
<tr>
<th>EC50 (static)</th>
<th>&gt;1.175 mg/kg (daphnia) (Toxicity to aquatic invertebrates)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aqua toxicity</td>
<td>≥0.008 mg/l (daphnia) (Daphnia Magna Reproduction Test)</td>
</tr>
<tr>
<td>Toxicity to Aquatic Plants (static)</td>
<td>&gt;0.26 mg/l (Plant) (Toxicity to algae)</td>
</tr>
</tbody>
</table>

128-37-0 Butylated Hydroxytoluene  
| Aqua toxicity (static) | 0.48 mg/l (daphnia) (Toxicity to aquatic invertebrates) |

- **Persistence and degradability** No further relevant information available.  
- **Behaviour in environmental systems:**  
- **Bioaccumulative potential** No further relevant information available.  
- **Mobility in soil** No further relevant information available.  
- **Additional ecological information:**  
- **General notes:**  
  Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water  
  Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.  
  Must not reach sewage water or drainage ditch undiluted or unneutralised.  
- **Results of PBT and vPvB assessment**  
  - **PBT:** Not applicable.  
  - **vPvB:** Not applicable.  
- **Other adverse effects** No further relevant information available.  

### 13 Disposal considerations  
- **Waste treatment methods**  
- **Recommendation**  
  Must not be disposed together with household garbage. Do not allow product to reach sewage system.  

- **European waste catalogue**  
  | HP3 | Flammable |
  | HP8 | Corrosive  |
  | HP13| Sensitising |

- **Uncleaned packaging:**  
- **Recommendation:** Disposal must be made according to official regulations.  

### 14 Transport information  
- **UN-Number**  
  - ADR, IMDG, IATA  
  - UN1987  
- **UN proper shipping name**  
  - ADR  
  - IMDG, IATA  
  - 1987 ALCOHOLS, N.O.S. (Ethyl Alcohol)  
  - ALCOHOLS, N.O.S. (Ethyl Alcohol)
**Transport hazard class(es)**

- **ADR, IMDG, IATA**

- **Class**: 3 Flammable liquids.

- **Label**: 3

- **Packing group**

- **ADR, IMDG, IATA**: III

- **Environmental hazards**: Not applicable.

- **Special precautions for user**

  - **Warning**: Flammable liquids.

- **Danger code (Kemler)**: 30

- **EMS Number**: F-E,S-D

- **Stowage Category**: B

- **Transport in bulk according to Annex II of Marpol and the IBC Code**: Not applicable.

- **Transport/Additional information**:

  - **ADR**

    - **Limited quantities (LQ)**: 5L
    - **Excepted quantities (EQ)**: Code: E1
      
      Maximum net quantity per inner packaging: 30 ml
      
      Maximum net quantity per outer packaging: 1000 ml

    - **Transport category**: 3
    - **Tunnel restriction code**: D/E

  - **IMDG**

    - **Limited quantities (LQ)**: 5L
    - **Excepted quantities (EQ)**: Code: E1
      
      Maximum net quantity per inner packaging: 30 ml
      
      Maximum net quantity per outer packaging: 1000 ml

- **UN "Model Regulation"**: UN 1987 ALCOHOLS, N.O.S. (ETHYL ALCOHOL), 3, III

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**15 Regulatory information**

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**

  - **Directive 2012/18/EU**

  - **Named dangerous substances - ANNEX I** None of the ingredients is listed.

  - **Seveso category P5c FLAMMABLE LIQUIDS**

  - **Qualifying quantity (tonnes) for the application of lower-tier requirements**: 5,000 t

  - **Qualifying quantity (tonnes) for the application of upper-tier requirements**: 50,000 t

  - **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3

  - **Chemical safety assessment**:

    Device is biocompatible when used as directed by dental professionals per ISO 10993-1

(Contd. on page 10)
16 Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

· Relevant phrases
  H225 Highly flammable liquid and vapour.
  H302 Harmful if swallowed.
  H312 Harmful in contact with skin.
  H314 Causes severe skin burns and eye damage.
  H315 Causes skin irritation.
  H317 May cause an allergic skin reaction.
  H318 Causes serious eye damage.
  H319 Causes serious eye irritation.
  H331 Toxic if inhaled.
  H400 Very toxic to aquatic life.
  H410 Very toxic to aquatic life with long lasting effects.
  H413 May cause long lasting harmful effects to aquatic life.

· Department issuing SDS: Regulatory Affairs
· Contact: Customer Service

· Abbreviations and acronyms:
  ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)
  IMDG: International Maritime Code for Dangerous Goods
  IATA: International Air Transport Association
  GHS: Globally Harmonised System of Classification and Labelling of Chemicals
  EINECS: European Inventory of Existing Commercial Chemical Substances
  ELINCS: European List of Notified Chemical Substances
  CAS: Chemical Abstracts Service (division of the American Chemical Society)
  VOC: Volatile Organic Compounds (USA, EU)
  LC50: Lethal concentration, 50 percent
  LD50: Lethal dose, 50 percent
  PBT: Persistent, Bioaccumulative and Toxic
  vPvB: very Persistent and very Bioaccumulative
  Flam. Liq. 2: Flammable liquids – Category 2
  Flam. Liq. 3: Flammable liquids – Category 3
  Acute Tox. 4: Acute toxicity – Category 4
  Acute Tox. 3: Acute toxicity – Category 3
  Skin Corr. 1A: Skin corrosion/irritation – Category 1A
  Skin Irrit. 2: Skin corrosion/irritation – Category 2
  Eye Dam. 1: Serious eye damage/eye irritation – Category 1
  Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
  Skin Sens. 1: Skin sensitisation – Category 1
  STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
  Aquatic Acute 1: Hazardous to the aquatic environment - acute aquatic hazard – Category 1
  Aquatic Chronic 1: Hazardous to the aquatic environment - long-term aquatic hazard – Category 1
  Aquatic Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4