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

- **Product identifier**
  - **Trade name:** Opal™ Seal™
  - **Article number:** OS/71022
  - **Index number:** SDS 265-001.09

- **Relevant identified uses of the substance or mixture and uses advised against**
  - Professional Orthodontic Primer and Sealant

- **Application of the substance / the mixture**
  - Professional Orthodontic Primer and Sealant

- **Details of the supplier of the safety data sheet**
  - **Manufacturer/Supplier:** Ultradent Products Inc.
    505 W. Ultradent Drive (10200 S)
    South Jordan, UT 84095-3942
    USA
    onlineordersupport@utradent.com

  - **EC Responsible Person**
    Ultradent Products GmbH
    Am Westhover Berg 30
    51149 Cologne Germany
    Email: infoDe@utradent.com
    Emergency Phone: +49(0)2203-35-92-0

- **Further information obtainable from:** Customer Service

- **Emergency telephone number:**
  - CHEMTREC (NORTH AMERICA) : (800) 424-9300
  - (INTERNATIONAL) : +(703) 527-3887

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

  STOT SE 3 H335 May cause respiratory irritation.

- **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**:
  - Methacrylic Acid
  - Trade Secret

- **Hazard statements**
  - H226 Flammable liquid and vapour.
  - H314 Causes severe skin burns and eye damage.
  - 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.
  - P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
  - P240 Ground and bond container and receiving equipment.
  - P241 Use explosion-proof [electrical/ventilating/lighting] equipment.
  - P242 Use non-sparking tools.
  - P243 Take action to prevent static discharges.
  - P260 Do not breathe dusts or mists.
  - P264 Wash thoroughly after handling.
  - P271 Use only outdoors or in a well-ventilated area.
  - P280 Wear protective gloves/protective clothing/eye protection/face protection.
  - P301+P330+P331 IF SWALLOWED: Rinse mouth. Do NOT induce vomiting.
  - P303+P361+P353 IF ON SKIN (or hair): Take off immediately all contaminated clothing. Rinse skin with water [or shower].
  - P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.
  - 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).
  - P363 Wash contaminated clothing before reuse.
  - P370+P378 In case of fire: Use for extinction: CO2, powder or water spray.
  - P403+P233 Store in a well-ventilated place. Keep container tightly closed.
  - P403+P235 Store in a well-ventilated place. Keep cool.
  - P405 Store locked up.
  - P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Additional information**: Contains Organophosphine Oxide. May produce an allergic reaction.

- **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.
Dangerous components:

<table>
<thead>
<tr>
<th>CAS</th>
<th>EINECS</th>
<th>Substance</th>
<th>Skin Irrit. 2, H315; Eye Irrit. 2, H319</th>
<th>Eye Irrit. 2, H319</th>
<th>Skin Corr. 1A, H314; Eye Dam. 1, H318; Acute Tox. 4, H312</th>
<th>Acute Tox. 3, H331; Skin Corr. 1A, H314; Eye Dam. 1, H318; Acute Tox. 4, H312</th>
<th>Acute Tox. 4, H302; Acute Tox. 4, H312</th>
<th>Acute Tox. 4, H312</th>
<th>Skin Sens. 1, H317; Aquatic Chronic 4, H413</th>
</tr>
</thead>
<tbody>
<tr>
<td>27813-02-1</td>
<td>248-666-3</td>
<td>Hydroxypropyl Methacrylate</td>
<td>&gt;10-%</td>
<td>≤25%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>64-17-5</td>
<td>200-578-6</td>
<td>Ethyl Alcohol</td>
<td>&gt;2.5-%</td>
<td>≤10%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>79-41-4</td>
<td>201-204-4</td>
<td>Methacrylic Acid</td>
<td>&gt;2.5-%</td>
<td>≤10%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2530-85-0</td>
<td>219-785-8</td>
<td>Silane</td>
<td>0-%</td>
<td>≤10%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>162881-26-7</td>
<td>423-340-5</td>
<td>Organophosphine Oxide</td>
<td>≤2.5%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Additional information: For the wording of the listed hazard phrases refer to section 16.

4 First aid measures

- Description of first aid measures
  - General information: Immediately remove any clothing soiled by the product.
  - After inhalation: In case of unconsciousness place patient stably in side position for transportation.
  - 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: Drink plenty of water and provide fresh air. Call for a doctor immediately.
  - Information for doctor:
    - Most important symptoms and effects, both acute and delayed: No further relevant information available.
    - Indication of any immediate medical attention and special treatment needed: No further relevant information available.

5 Firefighting measures

- Extinguishing media
  - Suitable extinguishing agents: CO₂ powder or water spray. Fight larger fires with water spray or alcohol resistant foam.
  - 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: Mouth respiratory protective device.

6 Accidental release measures

- Personal precautions, protective equipment and emergency procedures
  - 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).
  - Use neutralising agent.
  - Dispose contaminated material as waste according to item 13.
51.0.1 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.

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### 7 Handling and storage

- **Handling:**
  - **Precautions for safe handling:** No special precautions are necessary if used correctly.
  - **Information about fire - and explosion protection:**
    - Keep ignition sources away - Do not smoke.
    - Protect against electrostatic charges.

- **Conditions for safe storage, including any incompatibilities**

- **Storage:**
  - **Requirements to be met by storerooms and receptacles:** No special requirements.
  - **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 Orthodontic Primer and Sealant

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### 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:**

<table>
<thead>
<tr>
<th>Chemical</th>
<th>WEL (Great Britain) Long-term</th>
<th>WEL (Great Britain) Short-term</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-17-5 Ethyl Alcohol</td>
<td>1920 mg/m³, 1000 ppm</td>
<td>143 mg/m³, 40 ppm</td>
</tr>
<tr>
<td>79-41-4 Methacrylic Acid</td>
<td>72 mg/m³, 20 ppm</td>
<td></td>
</tr>
</tbody>
</table>

- **Additional information:** The lists valid during the making were used as basis.

- **Exposure controls**

- **Personal protective equipment:**

- **General protective and hygienic measures:**
  - 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 hands 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**

(Contd. on page 5)
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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value or Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Form:</strong></td>
<td>Viscous Liquid</td>
</tr>
<tr>
<td><strong>Colour:</strong></td>
<td>Yellow</td>
</tr>
<tr>
<td><strong>Odour:</strong></td>
<td>Acrylic</td>
</tr>
<tr>
<td><strong>Odour threshold:</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>pH-value:</strong></td>
<td>Not applicable (non-aqueous)</td>
</tr>
<tr>
<td><strong>Melting point/freezing point:</strong></td>
<td>Undetermined.</td>
</tr>
<tr>
<td><strong>Initial boiling point and boiling range:</strong></td>
<td>Undetermined.</td>
</tr>
<tr>
<td><strong>Flash point:</strong></td>
<td>37 °C</td>
</tr>
<tr>
<td><strong>Flammability (solid, gas):</strong></td>
<td>Not applicable.</td>
</tr>
<tr>
<td><strong>Decomposition temperature:</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Auto-ignition temperature:</strong></td>
<td>Product is not selfigniting.</td>
</tr>
<tr>
<td><strong>Explosion properties:</strong></td>
<td>Product is not explosive. However, formation of explosive air/vapour mixtures are possible.</td>
</tr>
<tr>
<td><strong>Explosion limits:</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Vapour pressure:</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Density:</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Relative density:</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Vapour density:</strong></td>
<td>Not determined.</td>
</tr>
<tr>
<td><strong>Evaporation rate:</strong></td>
<td>Not determined.</td>
</tr>
</tbody>
</table>
51.0.1 · 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) <15 %

Solids content: <50.0 %

· Other information No further relevant information available.

10 Stability and reactivity

· Reactivity No further relevant information available.

· Chemical stability

· Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.

· Possibility of hazardous reactions: No dangerous reactions known.

· Conditions to avoid: No further relevant information available.

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

64-17-5 Ethyl Alcohol

<table>
<thead>
<tr>
<th>Type</th>
<th>LD50</th>
<th>LC50 4 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>5,600 mg/kg (Guinea pig)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>3,400 mg/kg (mouse)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>7,060 mg/kg (rat)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>&gt;10,000 mg/l (Fish)</td>
<td></td>
</tr>
<tr>
<td>Inhalative</td>
<td>39 mg/l (mouse)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>20,000 mg/l (rat)</td>
<td></td>
</tr>
</tbody>
</table>

79-41-4 Methacrylic Acid

<table>
<thead>
<tr>
<th>Type</th>
<th>LD50</th>
<th>LC50 4 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>1,250 mg/kg (mouse)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1,060 mg/kg (rat)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>1,200 mg/kg (rabbit)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>86 mg/l (Fish)</td>
<td></td>
</tr>
<tr>
<td>Dermal</td>
<td>1,000 mg/kg (Guinea pig)</td>
<td></td>
</tr>
</tbody>
</table>
51.0.1

- Inhaling: LC50/4 h 500 mg/kg (rabbit)
  7.1 mg/l (rat)

162881-26-7 Organophosphate Oxide

- Oral: LD50 >2,000 mg/kg (rat)
  LC50 Fish >0.09 mg/l (Fish) (Toxicity to fish)

- Dermal: LD50 >2,000 mg/kg (rat)

- 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
  Based on available data, the classification criteria are not met.

- 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:
    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)
      EC50 45 mg/l (Algae) (Toxicity to algae)
    162881-26-7 Organophosphate Oxide
      EC50 (static) >1.175 mg/kg (daphnia) (Toxicity to aquatic invertebrates)
      Toxicity to Aquatic Plants (static) >0.26 mg/l (Plant) (Toxicity to algae)

- 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.
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

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

14 Transport information

- **UN-Number**
  - **ADR, IMDG, IATA:** UN2924

- **UN proper shipping name**
  - **ADR:** 2924 FLAMMABLE LIQUID, CORROSIVE, N.O.S. (METHACRYLIC ACID, STABILIZED, Ethyl Alcohol)
  - **IMDG, IATA:** FLAMMABLE LIQUID, CORROSIVE, N.O.S. (METHACRYLIC ACID, STABILIZED, Ethyl Alcohol)

- **Transport hazard class(es)**
  - **ADR**
    - Class 3 Flammable liquids.
    - Label 3+8
  - **IMDG**
    - Class 3 Flammable liquids.
    - Label 3/8
  - **IATA**
    - Class 3 Flammable liquids.
    - Label 3 (8)
51.0.1

· Packing group
  · ADR, IMDG, IATA
    III

· Environmental hazards:
  Not applicable.

· Special precautions for user
  · Hazard identification number (Kemler code):
    Warning: Flammable liquids.
    38
  · EMS Number:
    F-E,S-C
  · Stowage Category
    B
  · Stowage Code
    SW2 Clear of living quarters.

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

· Transport/Additional information:

  · ADR
    · Limited quantities (LQ)
      1L
    · Excepted quantities (EQ)
      Code: E2
      Maximum net quantity per inner packaging: 30 ml
      Maximum net quantity per outer packaging: 500 ml

  · Tunnel restriction code
    D/E

  · IMDG
    · Limited quantities (LQ)
      1L
    · Excepted quantities (EQ)
      Code: E2
      Maximum net quantity per inner packaging: 30 ml
      Maximum net quantity per outer packaging: 500 ml

· UN "Model Regulation":
  UN 2924 FLAMMABLE LIQUID, CORROSIVE, N.O.S.
  (METHACRYLIC ACID, STABILIZED, ETHYL ALCOHOL), 3 (8), III

15 Regulatory information

· Safety, health and environmental regulations/legislation specific for the substance or mixture
  · Directive 2012/18/EU
  · 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

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.
H335 May cause respiratory irritation.
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 - oral – Category 4
- Acute Tox. 3: Acute toxicity - inhalation – 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 Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4