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

· Product identifier
  · Trade name: Opal™ Seal™
  · Article number: OS/71022
  · Index number: SDS 265-001.08
· 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.
  - 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).
  - 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.

<table>
<thead>
<tr>
<th>CAS</th>
<th>Name</th>
<th>Hazard Classifications</th>
<th>Concentration</th>
</tr>
</thead>
<tbody>
<tr>
<td>27813-02-1</td>
<td>Hydroxpropyl Methacrylate</td>
<td>Skin Irrit. 2, Eye Irrit. 2, H315; Eye Irrit. 2, H319</td>
<td>&gt;10-≤25%</td>
</tr>
<tr>
<td>64-17-5</td>
<td>Ethyl Alcohol</td>
<td>Flam. Liq. 2, H225</td>
<td>&gt;2.5-≤10%</td>
</tr>
<tr>
<td>79-41-4</td>
<td>Methacrylic Acid</td>
<td>Acute Tox. 3, H331; Skin Corr. 1A, H314; Acute Tox. 4, H302;</td>
<td>&gt;2.5-≤10%</td>
</tr>
<tr>
<td>201-204-4</td>
<td></td>
<td>Acute Tox. 4, H312</td>
<td></td>
</tr>
<tr>
<td>2530-85-0</td>
<td>Silane</td>
<td>Skin Irrit. 2, Eye Irrit. 2, STOT SE 3, H335</td>
<td>&gt;20-≤10%</td>
</tr>
<tr>
<td>219-785-8</td>
<td></td>
<td>Skin Corr. 1A, H314</td>
<td></td>
</tr>
<tr>
<td>162881-26-7</td>
<td>Organophosphine Oxide</td>
<td>Skin Sens. 1, H317; Aquatic Chronic 4, H413</td>
<td>≤2.5%</td>
</tr>
<tr>
<td>423-340-5</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

(Contd. on page 3)
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.
  - 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: 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.
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)</th>
<th>Limit values</th>
</tr>
</thead>
<tbody>
<tr>
<td>64-17-5 Ethyl Alcohol</td>
<td>Long-term value: 1920 mg/m³, 1000 ppm</td>
<td></td>
</tr>
<tr>
<td>79-41-4 Methacrylic Acid</td>
<td>Short-term value: 143 mg/m³, 40 ppm</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Long-term value: 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 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

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.
### 9 Physical and chemical properties

- **Information on basic physical and chemical properties**
  - **General Information**
  - **Appearance:**
    - Form: Viscous Liquid
    - Colour: Yellow
  - **Odour:** Acrylic
  - **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:** 37 °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:** Not determined.
- **Relative density:** Not determined.
- **Vapour density:** Not determined.
- **Evaporation rate:** Not determined.

- **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 %

- **Solids content:** <50.0 %

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**Eye protection:**

- Tightly sealed goggles

**Body protection:** Protective work clothing
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:

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

64-17-5 Ethyl Alcohol

| Oral LD50                     | 5,600 mg/kg (Guinea pig) |
| Dermal LD50                   | 3,400 mg/kg (mouse)      |
| LC50 Fish                     | 7,060 mg/kg (rat)        |
| LC50 Fish                     | >10,000 mg/l (Fish)      |
| Inhalative LC50/4 h          | 39 mg/l (mouse)          |
|                              | 20,000 mg/l (rat)        |

79-41-4 Methacrylic Acid

| Oral LD50                     | 1,250 mg/kg (mouse) |
| Dermal LD50                   | 1,060 mg/kg (rat)  |
| LC50 Fish                     | 1,200 mg/kg (rabbit) |
| LC50 Fish                     | 86 mg/l (Fish)     |
| Dermal LD50                   | 1,000 mg/kg (Guinea pig) |
| LC50 Fish                     | 500 mg/kg (rabbit) |
| Inhalative LC50/4 h          | 7.1 mg/l (rat)      |

162881-26-7 Organophosphine 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.
48. 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 Organophosphine Oxide
EC50 (static) >1.175 mg/kg (daphnia) (Toxicity to aquatic invertebrates)
Aqua toxicity 0.008 mg/l (daphnia) (Daphnia Magna Reproduction Test)
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.

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

HP 3 Flammable
HP 8 Corrosive
### 14 Transport information

- **UN-Number**
  - UN2924

- **ADR proper shipping name**
  - ADR
    - Class: 3 Flammable liquids.
    - Label: 3+8

- **IMDG proper shipping name**
  - IMDG
    - Class: 3 Flammable liquids.
    - Label: 3/8

- **IATA proper shipping name**
  - IATA
    - Class: 3 Flammable liquids.
    - Label: 3 (8)

- **Packing group**
  - ADR, IMDG, IATA
    - III

- **Environmental hazards:**
  - Not applicable.

- **Special precautions for user**
  - Warning: Flammable liquids.
  - Danger code (Kemler): 38
  - EMS Number: F-E,S-C
  - Segregation groups: Acids
  - Stowage Category: A
  - Stowage Code: SW2 Clear of living quarters.

- **Transport in bulk according to Annex II of Marpol and the IBC Code**
  - Not applicable.
48. 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**
  - Tunnel restriction code 3 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 2924 FLAMMABLE LIQUID, CORROSIVE, N.O.S. (ETHYL ALCOHOL, METHACRYLIC ACID, STABILIZED), 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.
  - 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
Trade name: Opal® Seal®

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 Chronic 4: Hazardous to the aquatic environment - long-term aquatic hazard – Category 4