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

- Product identifier
  - Trade name: Opalescence™ Boost 40% Activator Gel
  - Article number: 71087
  - Index number: SDS 196-001.08
  - Relevant identified uses of the substance or mixture and uses advised against
    Professional Dental Tooth Whitening Activator
  - Application of the substance / the mixture
    Professional Dental Tooth Whitening Activator

- 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:
  - 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

  ![GHS03 flame over circle]
  Ox. Liq. 2  H272  May intensify fire; oxidiser.

  ![GHS05 corrosion]
  Skin Corr. 1A  H314  Causes severe skin burns and eye damage.

  ![GHS07]
  Acute Tox. 4  H302  Harmful if swallowed.
  Acute Tox. 4  H332  Harmful if inhaled.

- 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
Safety data sheet
according to 1907/2006/EC, Article 31

Trade name: Opalescence™ Boost 40% Activator Gel

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** GHS03, GHS05, GHS07
- **Signal word** Danger

- **Hazard-determining components of labelling:**
  - Potassium Hydroxide
  - Sodium Fluoride

- **Hazard statements**
  - H272 May intensify fire; oxidiser.
  - H302+H332 Harmful if swallowed or if inhaled.
  - H314 Causes severe skin burns and eye damage.

- **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.
  - P221 Take any precaution to avoid mixing with combustibles.
  - 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:**
  - EUH031 Contact with acids liberates toxic gas.

- **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:**
  - CAS: 56-81-5 Glycerine substance with a Community workplace exposure limit <80%
  - CAS: 7757-79-1 Potassium Nitrate Ox. Sol. 2, H272; Skin Irrit. 2, H315; STOT SE 3, H335-H336 <30%
  - CAS: 1310-58-3 Potassium Hydroxide Skin Corr. 1A, H314; Acute Tox. 4, H302 <30%
  - CAS: 7681-49-4 Sodium Fluoride Acute Tox. 3, H301; Acute Tox. 2, H310; Skin Irrit. 2, H315; Eye Irrit. 2, H319 <10%
  - Dimethicone Repr. 2, H361f; STOT RE 2, H373 <1%

- **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. Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.
- **After inhalation:**
  This product is a viscous gel, therefore chance of inhalation is extremely low. 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. If skin irritation continues, consult a doctor.
- **After eye contact:**
  Rinse opened eye for several minutes under running water. Then consult a doctor.
- **After swallowing:**
  Do not induce vomiting; call for medical help 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:**
  Water mist
  Foam, dry chemical, carbon dioxide
  Water fog
  Water spray
  Use fire extinguishing methods suitable to surrounding conditions.
- **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:**
  Dilute with plenty of water.
  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.
7 Handling and storage

- Handling:
  - Precautions for safe handling:
    Safety glasses should be used by the patient and doctor. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166 (EN).
    Ensure good ventilation/exhaustion at the workplace.
    Prevent formation of aerosols.
  - Information about fire - and explosion protection:
    Protect from heat.
    Keep respiratory protective device available.
  - 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:
      Store away from flammable substances.
      Do not store together with acids.
  - Further information about storage conditions:
    See product labelling.
    Keep container tightly sealed.
    Protect from heat and direct sunlight.
- Specific end use(s) Professional Dental Tooth Whitening Activator

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:
    | Chemical | Long-term/Short-term value |
    |----------|---------------------------|
    | 56-81-5 Glycerine | long-term: 10 mg/m³         |
    | WEL (Great Britain) |               |
    | 1310-58-3 Potassium Hydroxide | short-term: 2 mg/m³ |
    | WEL (Great Britain) |               |
  - 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 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.

· 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: Gel
  - Colour: Orange to Dark Red
  - Odour: Odourless
  - Odour threshold: Not determined.

· pH-value at 20 °C: 12

· Change in condition
  - Melting point/freezing point: Undetermined.
  - Initial boiling point and boiling range: Undetermined.

· Flash point: Not applicable.

· Flammability (solid, gas): Not applicable.

· Decomposition temperature: Not determined.

· Auto-ignition temperature: Product is not selfigniting.

· Explosive properties: Product does not present an explosion hazard.

· Explosion limits:
  - Lower: Not determined.
  - Upper: Not determined.

· Vapour pressure: Not determined.

· Density at 20 °C: 1.37 g/cm³
10 Stability and reactivity

- Reactivity: Stable
- Chemical stability
- Thermal decomposition / conditions to be avoided: No decomposition if used according to specifications.
- Possibility of hazardous reactions: Contact with acids releases toxic gases.
- Conditions to avoid:
  - Heat
  - Moisture
- Incompatible materials:
  - Organic materials
  - Metals
  - Acids
- Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

- Information on toxicological effects
- Acute toxicity
  - Harmful if swallowed or if inhaled.
- 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>407 mg/kg</td>
<td>&gt;0.243 mg/l (rat)</td>
</tr>
<tr>
<td>Dermal</td>
<td>2,059 mg/kg (rat)</td>
<td></td>
</tr>
<tr>
<td>Inhalative</td>
<td>&gt;0.243 mg/l (rat)</td>
<td></td>
</tr>
</tbody>
</table>

56-81-5 Glycerine

<table>
<thead>
<tr>
<th>Route</th>
<th>LD50</th>
<th>LC50/4 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>7,750 mg/kg (Guinea pig)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>4,100 mg/kg (mouse)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>5,570 mg/kg (rat)</td>
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</tr>
<tr>
<td></td>
<td>27,000 mg/kg (rabbit)</td>
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</tbody>
</table>
Trade name: Opalescence™ Boost 40% Activator Gel

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<thead>
<tr>
<th></th>
<th>LC50 Fish</th>
<th>LD50</th>
<th>Inhalative</th>
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</thead>
<tbody>
<tr>
<td>Dermal</td>
<td>&gt;5,000 mg/l (Fish)</td>
<td>&gt;21,900 mg/kg (rat)</td>
<td>10,000 mg/kg (rabbit)</td>
</tr>
<tr>
<td>Inhalative</td>
<td>LC50/4 h &gt;0.1425 mg/l (rat)</td>
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7757-79-1 Potassium Nitrate

<table>
<thead>
<tr>
<th></th>
<th>LD50</th>
<th>LC50 Fish</th>
<th>LD50</th>
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<tbody>
<tr>
<td>Oral</td>
<td></td>
<td>3,015 mg/kg (rat)</td>
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<tr>
<td>Dermal</td>
<td></td>
<td>1,901 mg/kg (rabbit)</td>
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<tr>
<td>LC50(Daphnia magna)</td>
<td>490 mg/l (daphnia)</td>
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1310-58-3 Potassium Hydroxide

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<thead>
<tr>
<th></th>
<th>LD50</th>
<th>LC50 Fish</th>
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<tbody>
<tr>
<td>Oral</td>
<td></td>
<td>214 mg/kg (rat)</td>
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<tr>
<td>Dermal</td>
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<td>80 mg/l (Fish)</td>
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12 Ecological information

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<tr>
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<tbody>
<tr>
<td>Aquatic toxicity</td>
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56-81-5 Glycerine

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<tbody>
<tr>
<td>EC50</td>
<td>&gt;10,000 mg/l (Bacteria)</td>
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<td></td>
<td>&gt;10,000 mg/l (daphnia)</td>
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7681-49-4 Sodium Fluoride

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<tbody>
<tr>
<td>EC50</td>
<td>272 mg/kg (Algae)</td>
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</tr>
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<td></td>
<td>98 mg/kg (daphnia)</td>
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<tr>
<td>Algae Toxicity (static)</td>
<td>7 mg/l (Algae)</td>
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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.
  Rinse off of bigger amounts into drains or the aquatic environment may lead to increased pH-values. A high pH-value harms aquatic organisms. In the dilution of the use-level the pH-value is considerably reduced, so that after the use of the product the aqueous waste, emptied into drains, is only low water-dangerous.

· 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
    Do not allow product to reach sewage system.
    Must not be disposed together with household garbage. Do not allow product to reach sewage system.

· European waste catalogue
  HP2 Oxidising
  HP5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity
  HP6 Acute Toxicity
  HP8 Corrosive
  HP12 Release of an acute toxic gas

· Uncleaned packaging:  
  · Recommendation: Disposal must be made according to official regulations.
  · Recommended cleansing agents: Water, if necessary together with cleansing agents.

14 Transport information

· UN-Number
  · ADR, IMDG, IATA UN1760

· UN proper shipping name
  · ADR 1760 CORROSIVE LIQUID, N.O.S. (POTASSIUM HYDROXIDE Mixture)
  · IMDG, IATA CORROSIVE LIQUID, N.O.S. (POTASSIUM HYDROXIDE Mixture)

· Transport hazard class(es)
  · ADR, IMDG, IATA

  · Class 8 Corrosive substances.
  · Label 8
### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
  - Directive 2012/18/EU
  - Seveso category P8 **OXIDISING LIQUIDS AND SOLIDS**
  - Qualifying quantity (tonnes) for the application of lower-tier requirements: 50 t
  - Qualifying quantity (tonnes) for the application of upper-tier requirements: 200 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**
    - H272 May intensify fire; oxidiser.
    - H301 Toxic if swallowed.
    - H302 Harmful if swallowed.
    - H310 Fatal in contact with skin.
    - H314 Causes severe skin burns and eye damage.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness.
H361f Suspected of damaging fertility.
H373 May cause damage to organs through prolonged or repeated exposure.

- **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
  - Ox. Liq. 2: Oxidizing liquids – Category 2
  - Ox. Sol. 2: Oxidizing solids – Category 2
  - Acute Tox. 3: Acute toxicity – Category 3
  - Acute Tox. 4: Acute toxicity – Category 4
  - Acute Tox. 2: Acute toxicity – Category 2
  - Skin Corr. 1A: Skin corrosion/irritation – Category 1A
  - Skin Irrit. 2: Skin corrosion/irritation – Category 2
  - Eye Irrit. 2: Serious eye damage/eye irritation – Category 2
  - Repr. 2: Reproductive toxicity – Category 2
  - STOT SE 3: Specific target organ toxicity (single exposure) – Category 3
  - STOT RE 2: Specific target organ toxicity (repeated exposure) – Category 2