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

- **Product identifier**
  - **Trade name:** Opalescence® Office Activator
  - **Article number:** 71195
  - **Index number:** SDS 349-001.04

- **Relevant identified uses of the substance or mixture and uses advised against**
  - Professional Dental Bleaching Gel, Part 2 of 2

- **Application of the substance / the mixture**
  - Professional Dental Bleaching Gel, Part 2 of 2

- **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@ultradent.com
  - **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

- **Further information obtainable from:**
  - **Emergency telephone number:**
    - During normal opening times: +1 (801) 553-4862
    - 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**

  GHS07

  Skin Irrit. 2  H315  Causes skin irritation.
  Eye Irrit. 2  H319  Causes serious eye 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 cosmetic in the finished state used in direct physical contact with the human body according to Art. 1.5 (c). Therefore, the product is exempted from the CLP labeling requirements, and no SDS is required by Regulation 1907/2006, Art. 2 (6b), REACH. Therefore, all given data, classification, and information on this SDS are provided solely on a voluntary basis.

- **Hazard pictograms**
  - GHS07
- **Signal word**
  - Warning
- **Hazard statements**
  - H315  Causes skin irritation.
  - H319  Causes serious eye irritation.
Trade name: Opalescence® Office Activator

- **Precautionary statements**
  - P264 Wash thoroughly after handling.
  - P280 Wear protective gloves / eye protection / face protection.
  - P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  - P332+P313 If skin irritation occurs: Get medical advice/attention.
  - P362+P364 Take off contaminated clothing and wash it before reuse.
  - P337+P313 If eye irritation persists: Get medical advice/attention.

- **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 EINECS: 200-289-5 Glycerine substance with a Community workplace exposure limit <95%
  - CAS: 7757-79-1 EINECS: 231-818-8 Potassium Nitrate Ox. Sol. 3, H272 <4%
  - CAS: 1310-73-2 EINECS: 215-185-5 Sodium Hydroxide Acute Tox. 3, H301; Acute Tox. 4, H312 <3%

- **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:** This product is a viscous gel, therefore chance of inhalation is not possible.
- **After skin contact:** Immediately wash with water and soap and rinse thoroughly.
- **After eye contact:** Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.
- **After swallowing:** If symptoms persist consult doctor.
- **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 spray
  - Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
6 Accidental release measures

- **Advice for firefighters:**
  - **Protective equipment:** No special measures required.

- **Personal precautions, protective equipment and emergency procedures** Not required.
- **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).
- **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.
    - See product labeling.
  - **Information about fire - and explosion protection:** No special measures required.
- **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 Dental Bleaching Gel, Part 2 of 2

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:**
    - **56-81-5 Glycerine**
      - WEL (Great Britain) Long-term value: 10 mg/m³
    - **1310-73-2 Sodium Hydroxide**
      - WEL (Great Britain) Short-term value: 2 mg/m³
  - **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:** Not required.


## 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

<table>
<thead>
<tr>
<th>Information on basic physical and chemical properties</th>
<th>General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>Form: Gel</td>
<td>Colour: Dark red</td>
</tr>
<tr>
<td>Odour: Odourless</td>
<td>Odour threshold: Not determined</td>
</tr>
<tr>
<td>pH-value at 20 °C: &gt;12</td>
<td></td>
</tr>
<tr>
<td>Change in condition</td>
<td></td>
</tr>
<tr>
<td>Melting point/freezing point: Undetermined</td>
<td>Initial boiling point and boiling range: Undetermined</td>
</tr>
<tr>
<td>Flash point: Not applicable</td>
<td>Flammability (solid, gas): Not applicable</td>
</tr>
<tr>
<td>Decomposition temperature: Not determined</td>
<td>Auto-ignition temperature: Product is not selfigniting</td>
</tr>
<tr>
<td>Explosive properties: Product does not present an explosion hazard</td>
<td></td>
</tr>
<tr>
<td>Explosion limits:</td>
<td></td>
</tr>
<tr>
<td>Lower: Not determined</td>
<td>Upper: Not determined</td>
</tr>
<tr>
<td>Vapour pressure: Not determined</td>
<td></td>
</tr>
<tr>
<td>Density at 20 °C: 1.3 g/cm³</td>
<td></td>
</tr>
</tbody>
</table>
### 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>Route</th>
<th>LD50</th>
<th>LC50/4 h</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>4,387-10,035 mg/kg</td>
<td>&gt;0.156 mg/l (rat)</td>
</tr>
<tr>
<td>Dermal</td>
<td>50,000 mg/kg (rabbit)</td>
<td>&gt;21,900 mg/kg (rat)</td>
</tr>
<tr>
<td>Inhalative</td>
<td>&gt;4,100 mg/kg (mouse)</td>
<td>&gt;0.1425 mg/l (rat)</td>
</tr>
</tbody>
</table>

**56-81-5 Glycerine**

<table>
<thead>
<tr>
<th>Route</th>
<th>LD50</th>
<th>LC50 Fish</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>7,750 mg/kg (Guinea pig)</td>
<td>&gt;5,000 mg/l (Fish)</td>
</tr>
<tr>
<td>Dermal</td>
<td>&gt;4,100 mg/kg (mouse)</td>
<td>&gt;27,000 mg/kg (rabbit)</td>
</tr>
<tr>
<td>Inhalative</td>
<td>&gt;5,570 mg/kg (rat)</td>
<td>&gt;10,000 mg/kg (rabbit)</td>
</tr>
<tr>
<td></td>
<td>&gt;4,100 mg/kg (mouse)</td>
<td>&gt;21,900 mg/kg (rat)</td>
</tr>
<tr>
<td></td>
<td>&gt;5,570 mg/kg (rat)</td>
<td>&gt;10,000 mg/kg (rabbit)</td>
</tr>
<tr>
<td></td>
<td>&gt;7,750 mg/kg (Guinea pig)</td>
<td>&gt;0.1425 mg/l (rat)</td>
</tr>
</tbody>
</table>

(Contd. on page 6)
### Safety data sheet

**Trade name: Opalescence® Office Activator**

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#### 7757-79-1 Potassium Nitrate

<table>
<thead>
<tr>
<th>Route</th>
<th>Endpoint</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>LD50</td>
<td>3,015 mg/kg (rat)</td>
</tr>
<tr>
<td></td>
<td>LC50 Fish</td>
<td>1,901 mg/kg (rabbit)</td>
</tr>
<tr>
<td>Dermal</td>
<td>LD50</td>
<td>&gt;5,000 mg/kg (rat)</td>
</tr>
<tr>
<td></td>
<td>LC50 (Daphnia magna)</td>
<td>490 mg/l (daphnia)</td>
</tr>
</tbody>
</table>

#### 1310-73-2 Sodium Hydroxide

<table>
<thead>
<tr>
<th>Route</th>
<th>Endpoint</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral</td>
<td>LD50</td>
<td>130-340 mg/kg (rat)</td>
</tr>
<tr>
<td></td>
<td>LC50 Fish</td>
<td>160 mg/l (Fish)</td>
</tr>
<tr>
<td>Dermal</td>
<td>LD50</td>
<td>1,350 mg/kg (rabbit)</td>
</tr>
<tr>
<td></td>
<td>Absolute lethal concentration</td>
<td>180 ppm (Fish)</td>
</tr>
</tbody>
</table>

### Primary irritant effect:
- **Skin corrosion/irritation**
  Causes skin irritation.
- **Serious eye damage/irritation**
  Causes serious eye irritation.
- **Respiratory or skin sensitisation**
  Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, 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**
    Based on available data, the classification criteria are not met.
  - **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.

### Ecological information

#### Toxicity
- **Aquatic toxicity:**

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>56-81-5 Glycerine</td>
<td>&gt;10,000 mg/l (Bacteria)</td>
</tr>
<tr>
<td></td>
<td>&gt;10,000 mg/l (daphnia)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Substance</th>
<th>EC50</th>
</tr>
</thead>
<tbody>
<tr>
<td>1310-73-2 Sodium Hydroxide</td>
<td>40.38 mg/l (Water Flea)</td>
</tr>
</tbody>
</table>

#### 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.
  - 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.
13 Disposal considerations

- Waste treatment methods
  - Recommendation
    Must not be disposed together with household garbage. Do not allow product to reach sewage system.
- Uncleaned packaging:
  - Recommendation: Disposal must be made according to official regulations.

14 Transport information

- UN-Number
  - ADR, IMDG, IATA UN1760
- UN proper shipping name
  - ADR 1760 CORROSIVE LIQUID, N.O.S. (SODIUM HYDROXIDE Mixture)
  - IMDG, IATA CORROSIVE LIQUID, N.O.S. (SODIUM HYDROXIDE Mixture)
- Transport hazard class(es)
  - ADR, IMDG, IATA
  - Class 8 Corrosive substances.
- Packing group
  - ADR, IMDG, IATA III
- Environmental hazards:
  - Not applicable.
- Special precautions for user
  - Warning: Corrosive substances.
  - EMS Number: F-A,S-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
  - UN "Model Regulation":
    UN 1760 CORROSIVE LIQUID, N.O.S. (SODIUM HYDROXIDE Mixture), 8, III
Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 21.11.2018
Revision: 02.10.2018

Trade name: Opalescence® Office Activator

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- REGULATION (EC) No 1907/2006 ANNEX XVII Conditions of restriction: 3
- Chemical safety assessment:
The product meets the toxicological profile required for cosmetics per the EU cosmetic regulation, Regulation (EC) No. 1223/2009.

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.
  H312 Harmful in contact with skin.

- 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. Sol. 3: Oxidizing solids – Category 3
  Acute Tox. 3: Acute toxicity – Category 3
  Acute Tox. 4: Acute toxicity – Category 4
  Skin Irrit. 2: Skin corrosion/irritation – Category 2
  Eye Irrit. 2: Serious eye damage/eye irritation – Category 2