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

· Product identifier

· Trade name: Opalescence™ PF, 10-20% Bleaching Gel (Regular, Mint or Melon)

· Article number: 13509, 13514, 13518, 39005, 39009, 39013, 39019, 39025, 39029, 71178, 71179, 71180

· Index number: SDS 14-001.17

· Relevant identified uses of the substance or mixture and uses advised against

Professional Dental Teeth Bleaching Gel

· Application of the substance / the mixture Professional Dental Teeth Bleaching Gel

· 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

  !

  GHS07

  Acute Tox. 4  H332  Harmful if inhaled.
  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-determining components of labelling:
  Carbamide Peroxide
  Sodium Hydroxide

(Contd. on page 2)
Trade name: Opalescence™ PF, 10-20% Bleaching Gel (Regular, Mint or Melon)

- **Hazard statements**
  - H332 Harmful if inhaled.
  - H315 Causes skin irritation.
  - H319 Causes serious eye 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.
  - P261 Avoid breathing dust/fume/gas/mist/vapours/spray.
  - P280 Wear protective gloves / eye protection / face protection.
  - 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.
  - P312 Call a POISON CENTER/doctor if you feel unwell.
  - P321 Specific treatment (see on this label).

- **Additional information:**
  - Contains Oils, Peppermint. 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>Dangerous components</th>
<th>Composition</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAS: 56-81-5</td>
<td>Glycerine</td>
</tr>
<tr>
<td>EINECS: 200-289-5</td>
<td>substance with a Community workplace exposure limit</td>
</tr>
<tr>
<td>CAS: 124-43-6</td>
<td>Carbamide Peroxide</td>
</tr>
<tr>
<td>EINECS: 204-701-4</td>
<td>&gt;10-≤20%</td>
</tr>
<tr>
<td>CAS: 1310-73-2</td>
<td>Sodium Hydroxide</td>
</tr>
<tr>
<td>EINECS: 215-185-5</td>
<td>Acute Tox. 3, H301; Skin Corr. 1A, H314; Acute Tox. 4, H312</td>
</tr>
<tr>
<td>CAS: 8006-90-4</td>
<td>Artificial Watermelon</td>
</tr>
<tr>
<td>EINECS: 282-015-4</td>
<td>Flam. Liq. 3, H26</td>
</tr>
<tr>
<td>CAS: 7681-49-4</td>
<td>Sodium Fluoride</td>
</tr>
<tr>
<td>EINECS: 231-667-8</td>
<td>Acute Tox. 3, H301; Acute Tox. 2, H310; Skin Irrit. 2, H315; Eye Irrit. 2, H319</td>
</tr>
<tr>
<td>CAS: 7757-79-1</td>
<td>Potassium Nitrate</td>
</tr>
<tr>
<td>EINECS: 231-818-8</td>
<td>Ox. Sol. 2, H272; Skin Irrit. 2, H315; STOT SE 3, H335-H336</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.
  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.
  In case of unconsciousness place patient stably in side position for transportation.
· 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. If symptoms persist, consult a doctor.
· After swallowing:
  If swallowed in large quantities seek medical attention.
· 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
· Special hazards arising from the substance or mixture No further relevant information available.
· Advice for firefighters:
· Protective equipment:
  Wear fully protective suit.
  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:
  Dispose contaminated material as waste according to item 13.
  Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
  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.
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>Substance</th>
<th>Limit Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>56-81-5 Glycerine</td>
<td>WEL (Great Britain) Long-term value: 10 mg/m³</td>
</tr>
<tr>
<td>1310-73-2 Sodium Hydroxide</td>
<td>WEL (Great Britain) Short-term value: 2 mg/m³</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 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.
Trade name: Opalescence™ PF, 10-20% Bleaching Gel (Regular, Mint or Melon)

- **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>· Appearance:</td>
<td></td>
</tr>
<tr>
<td>· Form:</td>
<td>Gel</td>
</tr>
<tr>
<td>· Colour:</td>
<td>Colourless</td>
</tr>
<tr>
<td>· Odour:</td>
<td>Product specific</td>
</tr>
<tr>
<td>· Odour threshold:</td>
<td>Not determined.</td>
</tr>
<tr>
<td>· pH-value at 20 °C:</td>
<td>5.3-7.5</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>· Change in condition</th>
<th>· General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Melting point/freezing point:</td>
<td>Undetermined.</td>
</tr>
<tr>
<td>· Initial boiling point and boiling range:</td>
<td>Undetermined.</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>· Flash point:</th>
<th>· General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Not applicable.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>· Flammability (solid, gas):</th>
<th>· General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Not applicable.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>· Decomposition temperature:</th>
<th>· General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Not determined.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>· Auto-ignition temperature:</th>
<th>· General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Product is not selfigniting.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>· Explosive properties:</th>
<th>· General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Product does not present an explosion hazard.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>· Explosion limits:</th>
<th>· General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Lower: Not determined.</td>
<td></td>
</tr>
<tr>
<td>· Upper: Not determined.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>· Vapour pressure:</th>
<th>· General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Not determined.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>· Density at 20 °C:</th>
<th>· General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>· 1.2-1.3 g/cm³</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>· Relative density</th>
<th>· General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Not determined.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>· Vapour density</th>
<th>· General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Not determined.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>· Evaporation rate</th>
<th>· General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Not determined.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>· Solubility in / Miscibility with water:</th>
<th>· General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Partly soluble.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>· Partition coefficient: n-octanol/water:</th>
<th>· General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Not determined.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>· Viscosity:</th>
<th>· General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Dynamic: Not determined.</td>
<td></td>
</tr>
<tr>
<td>· Kinematic: Not determined.</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>· Solvent content:</th>
<th>· General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>· Organic solvents: &lt;60 %</td>
<td></td>
</tr>
<tr>
<td>· Water: &lt;50 %</td>
<td></td>
</tr>
<tr>
<td>· VOC (EC) 0.00 %</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>· Solids content:</th>
<th>· General Information</th>
</tr>
</thead>
<tbody>
<tr>
<td>· &lt;60.0 %</td>
<td></td>
</tr>
</tbody>
</table>
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: No dangerous reactions known.
- Conditions to avoid: Excess heat
- Incompatible materials:
  - Strong Alkalis
  - Metals
- Hazardous decomposition products: No dangerous decomposition products known.

11 Toxicological information

- Information on toxicological effects
  - Acute toxicity: Harmful if inhaled.

- LD/LC50 values relevant for classification:

<table>
<thead>
<tr>
<th>ATE (Acute Toxicity Estimates)</th>
<th>Oral LD50</th>
<th>3,688-7,498 mg/kg</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dermal LD50</td>
<td>27,959 mg/kg (rabbit)</td>
<td></td>
</tr>
<tr>
<td>Inhalative LC50/4 h</td>
<td>&gt;0.403 mg/l (rat)</td>
<td></td>
</tr>
</tbody>
</table>

- 56-81-5 Glycerine

| Oral LD50                  | 7,750 mg/kg (Guinea pig) |
| Dermal LC50 Fish           | 4,100 mg/kg (mouse)      |
| Inhalative LC50/4 h        | 5,570 mg/kg (rat)        |
|                              | 27,000 mg/kg (rabbit)    |
|                              | >5,000 mg/l (Fish)       |

- 124-43-6 Carbamide Peroxide

| Oral LD50                  | >2,000 mg/kg (rat)       |
| Dermal LC50 Fish           | 130-340 mg/kg (rat)      |
| LD50                       | 160 mg/l (Fish)          |
| Absolute lethal concentration | 1,350 mg/kg (rabbit)    |
|                             | 180 ppm (Fish)           |

- 1310-73-2 Sodium Hydroxide

| Oral LD50                  | 2,490 mg/kg (mouse)      |
| Oral LD50                  | 2,426 mg/kg (rat)        |

(Contd. on page 7)
Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 03.10.2019  Revision: 18.07.2019

Trade name: Opalescence™ PF, 10-20% Bleaching Gel (Regular, Mint or Melon)

7681-49-4 Sodium Fluoride

<table>
<thead>
<tr>
<th>Type</th>
<th>50%</th>
<th>52 mg/kg (mouse)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Oral LD50</td>
<td></td>
<td></td>
</tr>
<tr>
<td>LC50 Fish (static)</td>
<td>17 mg/l (Fish)</td>
<td></td>
</tr>
<tr>
<td>Dermal LD50</td>
<td>175 mg/kg (rat)</td>
<td></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 (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**
  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.

12 Ecological information

- **Toxicity**

  **Aquatic toxicity:**

  56-81-5 Glycerine

<table>
<thead>
<tr>
<th>Type</th>
<th>EC50</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>&gt;10,000 mg/l (Bacteria)</td>
</tr>
<tr>
<td></td>
<td>&gt;10,000 mg/l (daphnia)</td>
</tr>
</tbody>
</table>

  1310-73-2 Sodium Hydroxide

<table>
<thead>
<tr>
<th>Type</th>
<th>EC50</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>40.38 mg/l (Water Flea)</td>
</tr>
</tbody>
</table>

  7681-49-4 Sodium Fluoride

<table>
<thead>
<tr>
<th>Type</th>
<th>EC50</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>272 mg/kg (Algae)</td>
</tr>
<tr>
<td></td>
<td>98 mg/kg (daphnia)</td>
</tr>
<tr>
<td></td>
<td>7 mg/l (Algae)</td>
</tr>
</tbody>
</table>

- **Persistence and degradability**
  No further relevant information available.
- **Behaviour in environmental systems:**
  No further relevant information available.
- **Mobility in soil**
  No further relevant information available.
- **Additional ecological information:**
  - **General notes:** Water hazard class 2 (German Regulation) (Self-assessment): hazardous for water Do not allow product to reach ground water, water course or sewage system. Danger to drinking water if even small quantities leak into the ground.
  - **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
  HP8 Corrosive

- 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 not regulated

- UN proper shipping name
  ADR, IMDG, IATA not regulated

- Transport hazard class(es)
  ADR, ADN, IMDG, IATA not regulated

- Packing group
  ADR, IMDG, IATA not regulated

- Environmental hazards:
  Not applicable.

- Special precautions for user
  Not applicable.

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

- UN "Model Regulation":
  not regulated

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.

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

- Chemical safety assessment:
  The 10-16% products meet 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
  H226 Flammable liquid and vapour.
Trade name: Opalescence™ PF, 10-20% Bleaching Gel (Regular, Mint or Melon)

H272 May intensify fire; oxidiser.
H301 Toxic if swallowed.
H304 May be fatal if swallowed and enters airways.
H310 Fatal in contact with skin.
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.
H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness.
H411 Toxic to aquatic life with long lasting effects.

· 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. 3: Flammable liquids – Category 3
  Ox. Sol. 2: Oxidizing solids – Category 2
  Ox. Sol. 3: Oxidizing solids – Category 3
  Acute Tox. 3: Acute toxicity – Category 3
  Acute Tox. 2: Acute toxicity – Category 2
  Acute Tox. 4: Acute toxicity – Category 4
  Skin Corr. 1A: Skin corrosion/irritation – Category 1A
  Skin Corr. 1B: Skin corrosion/irritation – Category 1B
  Skin Irrit. 2: Skin corrosion/irritation – Category 2
  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
  Asp. Tox. 1: Aspiration hazard – Category 1
  Aquatic Chronic 2: Hazardous to the aquatic environment - long-term aquatic hazard – Category 2