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

· Product identifier
  · Trade name: Ultradent® Porcelain Etch
  · Article number: 10324
  · Index number: SDS 4-001.16

· Relevant identified uses of the substance or mixture and uses advised against
  Professional Dental Acid Etching Solution

· Application of the substance / the mixture
  Professional Dental Acid Etching Solution

· 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:
  · 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

  GHS06 skull and crossbones

  Acute Tox. 3  H301  Toxic if swallowed.
  Acute Tox. 2  H310  Fatal in contact with skin.
  Acute Tox. 3  H331  Toxic if inhaled.

  GHS05 corrosion

  Skin Corr. 1A  H314  Causes severe skin burns and eye damage.
  Eye Dam. 1  H318  Causes serious eye damage.

· 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.

(Contd. on page 2)
Safety data sheet  
according to 1907/2006/EC, Article 31

Trade name: Ultradent™ Porcelain Etch

- **Hazard pictograms** GHS05, GHS06
- **Signal word** Danger

- **Hazard-determining components of labelling:**
  Hydrofluoric Acid

- **Hazard statements**
  H301+H331 Toxic if swallowed or if inhaled.
  H310 Fatal in contact with skin.
  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.
  P260 Do not breathe dusts or mists.
  P262 Do not get in eyes, on skin, or on clothing.
  P264 Wash thoroughly after handling.
  P270 Do not eat, drink or smoke when using this product.
  P271 Use only outdoors or in a well-ventilated area.
  P280 Wear protective gloves/protective clothing/eye protection/face protection.
  P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/doctor.
  P321 Specific treatment (see on this label).
  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.
  P311 Call a POISON CENTER/doctor.
  P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
  P361+P364 Take off immediately all contaminated clothing and wash it before reuse.
  P403+P233 Store in a well-ventilated place. Keep container tightly closed.
  P405 Store locked up.
  P501 Dispose of contents/container in accordance with local/regional/national/international regulations.

- **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: 7664-39-3 Hydrofluoric Acid
  - EINECS: 231-634-8 Acute Tox. 2, H300; Acute Tox. 1, H310; Acute Tox. 2, H330; Corr. 1A, H314
  - >2.5-≤10% Skin

- **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.
  Remove breathing equipment only after contaminated clothing have been completely removed.
  In case of irregular breathing or respiratory arrest provide artificial respiration.
· After inhalation:
  Supply fresh air or oxygen; call for doctor.
  In case of unconsciousness place patient stably in side position for transportation.
· After skin contact:
  Rub in Ca-gluconate solution or Ca-gluconate gel immediately.
  Immediately remove all soiled and contaminated clothing.
  Seek immediate medical advice.
  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:
  Do not induce vomiting; call for medical help immediately.
  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:
  Foam, dry chemical, carbon dioxide
  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: 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: No special measures required.
· 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:**
    - Ensure good ventilation/exhaustion at the workplace.
    - Open and handle receptacle with care.
    - Prevent formation of aerosols.
  - **Information about fire - and explosion protection:** Keep respiratory protective device available.

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

- **Storage:**
  - **Requirements to be met by storerooms and receptacles:** Unsuitable material for receptacle: glass or ceramic.
  - **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 Acid Etching Solution**

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:**

    | 7664-39-3 Hydrofluoric Acid |
    |----------------------------|
    | WEL (Great Britain)        |
    | Short-term value: 2.5 mg/m³, 3 ppm |
    | Long-term value: 1.5 mg/m³, 1.8 ppm |

  - **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.
      - Store protective clothing separately.
      - 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:**

    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.
9 Physical and chemical properties

<table>
<thead>
<tr>
<th>Physical and chemical properties</th>
<th>Details</th>
</tr>
</thead>
</table>
| **General Information** | **Appearance:**  
| **Form:** Gel  
| **Colour:** Yellow  
| **Odour:** Acidic  
| **Odour threshold:** Not determined. |
| **pH-value:** < 1.0 |
| **Change in condition** | **Melting point/freezing point:** Undetermined.  
| **Initial boiling point and boiling range:** 100 °C |
| **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:** 1.1 – 1.2 g/cm³ |
| **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:** | **Water:** <100 % |

(Contd. on page 6)
Safety data sheet
according to 1907/2006/EC, Article 31

Trade name: Ultradent™ Porcelain Etch

<table>
<thead>
<tr>
<th>VOC (EC)</th>
<th>0.00 %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Solids content:</td>
<td>&lt;21.0 %</td>
</tr>
<tr>
<td>Other information</td>
<td>No further relevant information available.</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:
  - Reacts with organic substances.
  - Reacts with strong alkali.
  - Reacts with acids.
  - Reacts with certain metals.
- Conditions to avoid: No further relevant information available.
- Incompatible materials: No further relevant information available.
- Hazardous decomposition products:
  - Hydrogen fluoride
  - Hydrogen
  - Corrosive gases/vapours

11 Toxicological information

- Information on toxicological effects
  - Acute toxicity
    Toxic if swallowed or if inhaled.
    Fatal in contact with skin.
  - LD/LC50 values relevant for classification:
    ATE (Acute Toxicity Estimates)
    | Mode     | LD50   | LC50   |
    |-----------|--------|--------|
    | Oral      | 51.4-58.2 mg/kg |
    | Dermal    | 51.4-58.2 mg/kg |
    | Inhalative| 5.14-5.82 mg/l |
  - 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 (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.
12 Ecological information

- Toxicity
- Aquatic toxicity: No further relevant information available.
- 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:
  Not hazardous for water.
  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.

<table>
<thead>
<tr>
<th>European waste catalogue</th>
</tr>
</thead>
<tbody>
<tr>
<td>HP6 Acute Toxicity</td>
</tr>
<tr>
<td>HP8 Corrosive</td>
</tr>
</tbody>
</table>

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

14 Transport information

- UN-Number: UN1790
- ADR, IMDG, IATA: 1790 HYDROFLUORIC ACID mixture

- Transport hazard class(es)
- ADR

| Class | 8 Corrosive substances. |

(Contd. on page 8)
**Trade name: Ultradent™ Porcelain Etch**

(Contd. of page 7)

| · **Label** | 8+6.1 |
| · **IMDG** | 8 Corrosive substances. |
| · Class | 8 Corrosive substances. |
| · Label | 8/6.1 |

| · **IATA** | 8 Corrosive substances. |
| · Class | 8 (6.1) |
| · Label | 8 (6.1) |

| · **Packing group** | II |
| · **ADR, IMDG, IATA** | II |

| · **Environmental hazards:** | Not applicable. |
| · **Special precautions for user** | Warning: Corrosive substances. |
| · **EMS Number:** | F-A,S-B |
| · **Segregation groups** | Strong acids |
| · **Stowage Category** | D |
| · **Stowage Code** | SW1 Protected from sources of heat. |
| · **Handling Code** | SW2 Clear of living quarters. |
| · **H2 Keep as cool as reasonably practicable** |

| · **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 |
| · **Transport category** | 2 |
| · **Tunnel restriction code** | 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 1790 HYDROFLUORIC ACID MIXTURE, 8 (6.1), II |

(Contd. on page 9)
15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
  - Directive 2012/18/EU
  - Seveso category H2 ACUTE TOXIC
  - 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 a strong acid and is extremely toxic. It is to be used only as directed with PPE, and only by licensed dental professionals.

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
  H300 Fatal if swallowed.
  H310 Fatal in contact with skin.
  H314 Causes severe skin burns and eye damage.
  H330 Fatal if inhaled.

- 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
  Acute Tox. 2: Acute toxicity - oral – Category 2
  Acute Tox. 3: Acute toxicity - oral – Category 3
  Acute Tox. 1: Acute toxicity - dermal – Category 1
  Skin Corr. 1A: Skin corrosion/irritation – Category 1A
  Eye Dam. 1: Serious eye damage/eye irritation – Category 1