

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

Printing date 14.12.2018

Revision: 08.10.2018

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

· **Product identifier**

· **Trade name:** Ultradent® Porcelain Etch

· **Article number:** 10324

· **Index number:** SDS 4-001.15

· **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 Westhoyer 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.

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- **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.
P301+P310 IF SWALLOWED: Immediately call a POISON CENTER/ doctor.
P321 Specific treatment (see on this label).
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.
P361+P364 Take off immediately all contaminated clothing and wash it before reuse.
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	>2.5-≤10%
EINECS: 231-634-8	Acute Tox. 2, H300; Acute Tox. 1, H310; Acute Tox. 2, H330; Skin Corr. 1A, H314	

- **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.

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- 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.

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- 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/m ³ , 3 ppm
	Long-term value: 1.5 mg/m ³ , 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:**



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

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9 Physical and chemical properties

· Information on basic physical and chemical properties	
· 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/cm ³
· 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 %
VOC (EC)	0.00 %
Solids content:	<21.0 %
· Other information	No further relevant information available.

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.

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- 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)

Oral	LD50	51.4-58.2 mg/kg
Dermal	LD50	51.4-58.2 mg/kg
Inhalative	LC50/4 h	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.

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· **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 6	Acute Toxicity
HP 8	Corrosive

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

14 Transport information

- **UN-Number**
- **ADR, IMDG, IATA** UN1790

- **UN proper shipping name**
- **ADR** 1790 HYDROFLUORIC ACID mixture
- **IMDG, IATA** HYDROFLUORIC ACID mixture

· **Transport hazard class(es)**· **ADR**

- **Class** 8 Corrosive substances.
- **Label** 8+6.1

· **IMDG**

- **Class** 8 Corrosive substances.
- **Label** 8/6.1

· **IATA**

- **Class** 8 Corrosive substances.
- **Label** 8 (6.1)

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

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· Environmental hazards:	Not applicable.
· Special precautions for user	Warning: Corrosive substances.
· Danger code (Kemler):	86
· EMS Number:	F-A,S-B
· Segregation groups	Acids
· Stowage Category	D
· Stowage Code	SW1 Protected from sources of heat. SW2 Clear of living quarters.
· Handling Code	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

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.

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· **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 – Category 2

Acute Tox. 3: Acute toxicity – Category 3

Acute Tox. 1: Acute toxicity – Category 1

Skin Corr. 1A: Skin corrosion/irritation – Category 1A

Eye Dam. 1: Serious eye damage/eye irritation – Category 1

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