

safety data sheet

to product

Ultradent UltraEZ™

1. Identification of the substance / preparation and company

Emergency number:

Tox Info Suisse, Freiestrasse 16, 8032 Zürich; Tox-Info Suisse: 145 (24h-operation); info@toxinfo.ch;
In case of emergency: Tel. 145; (abroad: +41 44 251 51 51); information: +41 44 251 66 66

Company name:



abc dental ag

Gaswerkstrasse 6, 8952 Schlieren
Tel. 044 755 51 00, Fax 044 755 51 01



Condor Dental Research CO Sàrl

Ch. des Cibleries 2, CP 300, 1896 Vouvry
Tel. 024 482 61 61, Fax 024 482 61 69



Curaden AG Dentaldepot

Riedstrasse 12, 8953 Dietikon
Tel. 041 319 45 00, Fax 041 319 45 90



dema dent AG

Furtbachstrasse 16, 8107 Buchs
Tel. 044 838 65 65, Fax 044 838 65 66



Flexdental Services SA

Route de la Corniche 1, 1066 Epalinges
Tel. 0848 336 825, Fax 021 907 67 02



Jordi Röntgentechnik AG

Dammstrasse 70, 4142 Münchenstein
Tel. 061 417 93 93, Fax 061 417 93 94



Kaladent AG

Schachenstrasse 2, 9016 St. Gallen
Tel. 071 282 80 80, Fax 071 282 80 81



Lometral AG

Binzenholzstrasse 20, 5704 Egliswil
Tel. 062 775 05 05, Fax 062 775 33 07



Novadent AG

Sägereistrasse 17, 8152 Glattbrugg
Tel. 044 880 20 20, Fax 044 811 04 40



Smart Dentist AG

Verenastrasse 4b, 8832 Wollerau
Tel. 044 726 20 20, Fax 044 726 20 25

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

Printing date 23.04.2019

Revision: 12.12.2018

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

- **Product identifier**
- **Trade name:** UltraEZ™
- **Article number:** 13588, 41902
- **Index number:** SDS 134-001.08
- **Relevant identified uses of the substance or mixture and uses advised against**
Professional Tooth Desensitizing Gel
- **Application of the substance / the mixture** Professional Tooth Desensitizing 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@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**
The product is not classified, according to the CLP regulation.

- **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.
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void
- **Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

GB2

(Contd. on page 2)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 23.04.2019

Revision: 12.12.2018

Trade name: UltraEZ™

(Contd. of page 1)

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	<80%
CAS: 7757-79-1 EINECS: 231-818-8	Potassium Nitrate ⚠ Ox. Sol. 2, H272; ⚠ Skin Irrit. 2, H315; STOT SE 3, H335-H336	≤3%
CAS: 1310-73-2 EINECS: 215-185-5	Sodium Hydroxide ⚠ Acute Tox. 3, H301; ⚠ Acute Tox. 4, H312	≤2.5%
CAS: 7681-49-4 EINECS: 231-667-8	Sodium Fluoride ⚠ Acute Tox. 3, H301; Acute Tox. 2, H310; ⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319	0.25%

- **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:** No special measures required.
- **After inhalation:** This product is a viscous gel, therefore chance of inhalation is extremely low.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **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:** Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters:**
- **Protective equipment:** No special measures required.

6 Accidental release measures

- **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.

GB2

(Contd. on page 3)

Safety data sheet

according to 1907/2006/EC, Article 31

Printing date 23.04.2019

Revision: 12.12.2018

Trade name: UltraEZ™

(Contd. of page 2)

7 Handling and storage

- **Handling:**
- **Precautions for safe handling:** No special measures required.
- **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.
- **Specific end use(s)** Professional Tooth Desensitizing Gel

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:**

The usual precautionary measures are to be adhered to when handling chemicals.

- **Respiratory protection:** Not required.

- **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.

- **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:** Goggles recommended during refilling

- **Body protection:** Protective work clothing

9 Physical and chemical properties

- **Information on basic physical and chemical properties**

- **General Information**

- **Appearance:**

Form: Gel

(Contd. on page 4)

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

Printing date 23.04.2019

Revision: 12.12.2018

Trade name: UltraEZ™

(Contd. of page 3)

· Colour:	Colourless
· Odour:	Odourless
· Odour threshold:	Not determined.
· pH-value:	6-7.5
· 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:	1.24 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:	
Organic solvents:	<75 %
Water:	<45 %
VOC (EC)	0.00 %
· Solids content:	<20.0 %
· 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:** 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.

GB2

(Contd. on page 5)

Safety data sheet
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Revision: 12.12.2018

Trade name: UltraEZ™

(Contd. of page 4)

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)

Oral	LD50	3,683-6,980 mg/kg
Dermal	LD50	29,167 mg/kg (rabbit)
Inhalative	LC50/4 h	>0.233 mg/l (rat)

56-81-5 Glycerine

Oral	LD50	7,750 mg/kg (Guinea pig)
		4,100 mg/kg (mouse)
		5,570 mg/kg (rat)
		27,000 mg/kg (rabbit)
Dermal	LC50 Fish	>5,000 mg/l (Fish)
	LD50	>21,900 mg/kg (rat)
Inhalative	LC50/4 h	10,000 mg/kg (rabbit)
		>0.1425 mg/l (rat)

7757-79-1 Potassium Nitrate

Oral	LD50	3,015 mg/kg (rat)
		1,901 mg/kg (rabbit)
Dermal	LC50 Fish	1,378 mg/l (Fish)
	LD50	>5,000 mg/kg (rat)
	LC50(Daphnia magna)	490 mg/l (daphnia)

1310-73-2 Sodium Hydroxide

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

- **Primary irritant effect:**
- **Skin corrosion/irritation** Based on available data, the classification criteria are not met.
- **Serious eye damage/irritation** Based on available data, the classification criteria are not met.
- **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.

GB2

(Contd. on page 6)

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

Printing date 23.04.2019

Revision: 12.12.2018

Trade name: UltraEZ™

(Contd. of page 5)

12 Ecological information

- **Toxicity**

- **Aquatic toxicity:**

56-81-5 Glycerine

EC50	>10,000 mg/l (Bacteria)
	>10,000 mg/l (daphnia)

1310-73-2 Sodium Hydroxide

EC50	40.38 mg/l (Water Flea)
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- **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.

- **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** Smaller quantities can be disposed of with household waste.

- **Uncleaned packaging:**

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

14 Transport information

- **UN-Number**

- **ADR, ADN, IMDG, IATA** not regulated

- **UN proper shipping name**

- **ADR, ADN, IMDG, IATA** not regulated

- **Transport hazard class(es)**

- **ADR, ADN, IMDG, IATA**

- **Class** 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.

(Contd. on page 7)

GB2

Safety data sheet
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Printing date 23.04.2019

Revision: 12.12.2018

Trade name: UltraEZ™

(Contd. of page 6)

· **UN "Model Regulation":** not regulated

15 Regulatory information

· **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.
H310 Fatal in contact with skin.
H312 Harmful in contact with skin.
H315 Causes skin irritation.
H319 Causes serious eye irritation.
H335 May cause respiratory irritation.
H336 May cause drowsiness or dizziness.

· **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. 2: Oxidizing solids – Category 2
Acute Tox. 3: Acute toxicity – Category 3
Acute Tox. 2: Acute toxicity – Category 2
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
STOT/SE 3: Specific target organ toxicity (single exposure) – Category 3

GB2