

## Safety Data Sheet according to WHS Regulations

Printing date 27.07.2023

Revision: 27.07.2023

### 1 Identification

- **Product identifier**
- **Trade name:** UltraEZ™
- **Article number:** SDS 134-001.08R02, 41902, 13588
- **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  
Ultradent Australia Pty Ltd.  
Level 22/2 Market Street  
Sydney NSW 2000  
Australia  
Email: info.anz@ultradent.com  
Toll Free: 1-800-290929
- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**  
CHEMTREC (NORTH AMERICA) : (800) 424-9300  
(INTERNATIONAL) : +(703) 527-3887

### 2 Hazard(s) Identification

- **Classification of the substance or mixture**  
The product is not classified, according to the Globally Harmonised System (GHS).
- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** Void
- **Signal word** Void
- **Hazard statements** Void

### 3 Composition and Information on Ingredients

- **Chemical characterisation:** Mixtures
- **Description:** Mixture of substances listed below with nonhazardous additions.

· **Dangerous components:**

56-81-5	Glycerin	30-60%
	⚠ Serious eye damage/irritation – Category 2A, H319	
7757-79-1	Potassium Nitrate	<10%
	⚠ Ox. Sol. 2, H272; ⚠ Skin Irrit. 2, H315; ⚠ Serious eye damage/irritation – Category 2A, H319; STOT SE 3, H335-H336	

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1310-73-2	Sodium Hydroxide	≥1-<3%
	⚠ Acute Tox. 3, H301; ⚠ Skin Corr. 1A, H314; Eye Dam. 1, H318; ⚠ Acute Tox. 4, H312	
7681-49-4	Sodium Fluoride	<10%
	⚠ Acute Tox. 3, H301; Acute Tox. 2, H310; ⚠ Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319	

· **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 4 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 Fire Fighting Measures

- **Suitable extinguishing agents:** Use fire extinguishing methods suitable to surrounding conditions.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **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.

### 7 Handling and Storage

- **Handling:**
- **Precautions for safe handling:**  
See product labeling.  
No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **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.

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· **Specific end use(s)** Professional Tooth Desensitizing Gel

### 8 Exposure controls and personal protection

· **Additional information about design of technical facilities:** No further data; see item 7.· **Ingredients with limit values that require monitoring at the workplace:**

#### 56-81-5 Glycerin

TWA Short-term value: 10 mg/m<sup>3</sup>WES Long-term value: 10 mg/m<sup>3</sup>  
inhalable dust

#### 1310-73-2 Sodium Hydroxide

WES Peak limitation: 2 mg/m<sup>3</sup>· **Additional information:** The lists valid during the making were used as basis.· **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

· **General Information**· **Appearance:**· **Form:** Gel· **Colour:** Colourless· **Odour:** Odourless· **Odour threshold:** Not determined.· **pH-value:** Not determined.· **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.

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- **Explosion limits:**
- **Lower:** Not determined.
- **Upper:** Not determined.
- **Vapour pressure:** Not determined.
- **Density at 20 °C:** 1.23 g/cm<sup>3</sup>
- **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.
- **Other information** No further relevant information available.

## 10 Stability and Reactivity

- **Reactivity** No further relevant information available.
- **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)

Oral	LD50	4,815-12,593 mg/kg
Dermal	LD50	50,000 mg/kg

#### 56-81-5 Glycerin

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

#### 7757-79-1 Potassium Nitrate

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

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	LC50(Daphnia magna)	490 mg/l (daphnia)
<b>1310-73-2 Sodium Hydroxide</b>		
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)
<b>7681-49-4 Sodium Fluoride</b>		
Oral	LD50	52 mg/kg (mouse)
	LC50 Fish (static)	17 mg/l (Fish)
Dermal	LD50	175 mg/kg (rat)

- **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.
- **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

· <b>Aquatic toxicity:</b>	
<b>56-81-5 Glycerin</b>	
EC50	>10,000 mg/kg (Bacteria)
<b>1310-73-2 Sodium Hydroxide</b>	
EC50	40.38 mg/kg (Water Flea)
<b>7681-49-4 Sodium Fluoride</b>	
EC50	272 mg/kg (Algae)
	98 mg/kg (daphnia)
Algae Toxicity (static)	7 mg/l (Algae)

- **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.

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### 13 Disposal considerations

- **Waste treatment methods**
- **Recommendation**  
Dispose of contents/container in accordance with international, federal, state, and local regulations.
- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### 14 Transport information

· <b>UN-Number</b>	
· <b>ADG, ADN, IMDG, IATA</b>	not regulated
· <b>UN proper shipping name</b>	
· <b>ADG, ADN, IMDG, IATA</b>	not regulated
· <b>Transport hazard class(es)</b>	
· <b>ADG, ADN, IMDG, IATA</b>	
· <b>Class</b>	not regulated
· <b>Packing group</b>	
· <b>ADG, IMDG, IATA</b>	not regulated
· <b>Environmental hazards:</b>	Not applicable.
· <b>Special precautions for user</b>	Not Applicable
· <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>UN "Model Regulation":</b>	not regulated

### 15 Regulatory information

· <b>Safety, health and environmental regulations/legislation specific for the substance or mixture</b>
· <b>Australian Inventory of Industrial Chemicals</b> All ingredients are listed.
· <b>Standard for the Uniform Scheduling of Medicines and Poisons</b> None of the ingredients is listed.
· <b>Australia: Priority Existing Chemicals</b> None of the ingredients is listed.
· <b>Directive 2012/18/EU</b>
· <b>Named dangerous substances - ANNEX I</b> None of the ingredients is listed.
· <b>Chemical safety assessment:</b> 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.

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· **Relevant phrases from Section 3**

H272 May intensify fire; oxidizer.  
 H301 Toxic if swallowed.  
 H310 Fatal in contact with skin.  
 H312 Harmful in contact with skin.  
 H314 Causes severe skin burns and eye damage.  
 H315 Causes skin irritation.  
 H318 Causes serious eye damage.  
 H319 Causes serious eye irritation.  
 H335 May cause respiratory irritation.  
 H336 May cause drowsiness or dizziness.

· **Department issuing SDS:** Environmental, Health, and Safety

· **Contact:** Customer Service

· **Abbreviations and acronyms:**

ADR: Accord relatif au transport international 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  
 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)  
 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 Corr. 1A: Skin corrosion/irritation – Category 1A  
 Skin Irrit. 2: Skin corrosion/irritation – Category 2  
 Eye Dam. 1: Serious eye damage/eye irritation – Category 1  
 Serious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A  
 STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· **\* Data compared to the previous version altered.**

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