

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 01/23/2007

SDS No : 134-001.4

Date Revised : 05/19/2015

Revision No : 4

UltraEz® and UltraEz® Tray Delivery

SECTION 1 : Identification of the substance/preparation and of the company/undertaking

1.1. Product identifier

Product code : TL/13588, UV/41902
Product name : UltraEz® and UltraEz® Tray Delivery
Product description : Sustained release potassium nitrate gel with fluoride

1.2. Relevant identified uses of the substance or mixture and uses advised against

Relevant identified uses : Professional Tooth Desensitizing Gel

1.3. Details of the supplier of the safety data sheet

Manufacturer

Ultradent Products, Inc.
 505 W. 10200 S.
 South Jordan, UT 84095

Distributor

Ultradent Products GmbH
 Am Westhover Berg 30
 51149 Cologne Germany
 Email: infoDE@ultradent.com
Emergency Phone : +49(0)2203-35-92-0

1.4. Emergency telephone number

CHEMTREC (NORTH AMERICA) : (800) 424 - 9300
(INTERNATIONAL) : +1(703) 527 - 3887

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Directive 1999/45/EC

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.
 This material is not considered hazardous to health.

Classification according to Regulation (EC) No 1272/2008 [CLP]

Health : None

2.2. Label elements

Classification according to Directive 1999/45/EC : This material is not considered to be hazardous for the health.

Classification according to Regulation (EC) No 1272/2008 [CLP]

Hazard statement(s) : 9502HLMN: This Material is not considered to be hazardous for the health.

Precautionary statement(s)

Prevention : P280: Wear protective gloves/protective clothing/eye protection/face protection.

Response : P305: IF IN EYES:
 P351: Rinse cautiously with water for several minutes.
 P302+P352: IF ON SKIN: Wash with plenty of soap and water.
 P332+P313: If skin irritation occurs: Get medical advice/attention.

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Storage : P273: Avoid release to the environment.
Disposal : P501: Dispose of in compliance with governmental regulation.
 (EC1975L0442-20/11/2003)

2.3. Other hazards

Immediate concerns : None

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
Sodium Hydroxide	1310-73-2	215-185-5	< 5	C; R34	Skin Corr., Cat. 1A; H314
Sodium Fluoride	007681-49-4	231-667-8	< 1	T, Xi; R25; R32; R36/38	Acute Tox. (O), Cat. 3; Eye Irr., Cat. 2; Skin Irr., Cat. 2; H301; H315; H319
Potassium Nitrate	7757-79-1	231-818-8	< 5	O, Xi; R36/37/38; R22	Oxid. Sol., Cat. 3; H272

For full text of H-statements and R-phrases: see SECTION 16.

SECTION 4: First aid measures

4.1. Description of first aid measures

Following eyes : Flush eyes with water. Get medical attention if irritation develops or persists.

Following skin : Wash with soap and water. Get medical attention if irritation develops or persists.

Following ingestion : If swallowed in small quantity the product is harmless, otherwise consult a doctor.

Following inhalation : No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of dusts or

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fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

4.2. Most important symptoms and effects, both acute and delayed

- Eyes** : May cause mild irritation.
- Skin** : Prolonged skin contact may cause skin irritation.
- Ingestion** : May be harmful if swallowed in large quantities.
- Inhalation** : None expected for this product.

4.3. Indication of any immediate medical attention and special treatment needed

- Notes to physician** : Not Applicable

SECTION 5: Fire fighting measures

5.1. Extinguishing media

- Extinguishing media** : Please see Fire Fighting Equipment under Section 5.3.

5.2. Special hazards arising from the substance or mixture

- Explosion hazards** : Not Determined
- Fire explosion** : Not Determined
- Sensitive to static discharge** : Not Determined
- Sensitivity to impact** : Not Determined

5.3. Advice for firefighters

- Fire fighting procedures** : General: Evacuate all personnel; use protective equipment for fire-fighting. Use self-contained breathing apparatus when the product is involved in fire.
- Fire fighting equipment** : Water spray, fog, or mist, foam, dry chemical, carbon dioxide(CO₂)

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General procedures** : Refer to Section 8 for Personal Protective Equipment.

6.2. Environmental precautions

- Water spill** : Do not allow to enter sewers or drains that may lead to waterways.

6.3. Methods and material for containment and cleaning up

- Small spill** : Wipe up with cloth, soap and water.
- Large spill** : Collect in tightly closed containers.

6.4. Reference to other sections

- Reference to other sections** : Not Applicable

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- General procedures** : Avoid contact with eyes, skin and clothing.

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Handling : Use suitable protective equipment.

Storage : See product labeling.

7.2. Conditions for safe storage, including any incompatibilities

Shelf life : See product labeling

7.3. Specific end use(s)

Specific end use(s) : Professional Tooth Desensitizing Gel

SECTION 8: Exposure controls / personal protection

8.1. Control parameters

Control parameters : Not Determined

8.2. Exposure controls

Eye/face protection : Wear eye protection

Skin protection : Wear suitable protective clothing and gloves.

Respiratory protection : Good general ventilation should be sufficient to control airborne levels.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state : Gel

Colour : Colorless

Odour : Odorless or no characteristic odor

pH : 6.0 to 7.5

9.2. Other information

Percent volatile : Not Determined

SECTION 10: Stability and reactivity

10.1. Reactivity

Reactivity : Stable

10.2. Chemical stability

Chemical stability : Stable when stored and handled under recommended conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization : None

10.4. Conditions to avoid

Conditions to avoid : Avoid strong bases, Metals. Excess heat, exposure to moist air or water.

10.5. Incompatible materials

Incompatible materials : Strong caustics, most metals.

10.6. Hazardous decomposition products

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Hazardous decomposition products : None known.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute

Notes : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

SECTION 12: Ecological information

12.1. Toxicity

Toxicity : Not Determined

Aquatic toxicity (acute)

96-hour LC₅₀ : Not Determined

48-hour EC₅₀ : Not Determined

96-hour EC₅₀ : Not Determined

12.2. Persistence and degradability

Persistence and degradability : Not Determined

12.3. Bioaccumulative potential

Bioaccumulative potential : Not Determined

12.4. Mobility in soil

Mobility in soil : Not Determined

12.5. Results of PBT and vPvB assessment

Results of PBT and vPvB assessment : Not Determined

12.6. Other adverse effects

Environmental data : Not defined

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Disposal method : Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

SECTION 14: Transport information

14.1. UN number

UN number : N/A

14.2. UN proper shipping name

UN proper shipping name : Not Dangerous Goods

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14.3. Transport hazard class(es)

Hazard classification : N/A

14.4. Packing group

Packing group : N/A

14.5. Environmental hazards

Marine pollutant #1 : N/A

14.6. Special precautions for user

ADR - road : Not Dangerous Goods

RID - rail : Not Dangerous Goods

IMDG - sea : Not Dangerous Goods

IATA - air : Not Dangerous Goods

14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code

Transport in bulk : Not Dangerous Goods

SECTION 15: Regulatory information

15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

RoHS : Please refer to Medical Devices Directive 93/42/EEC

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) : R22: Harmful if swallowed.
 R25: Toxic if swallowed.
 R32: Contact with acids liberates very toxic gas.
 R34: Causes burns.
 R36/37/38: Irritating to eyes, respiratory system and skin.
 R36/38: Irritating to eyes and skin.
 Acute Tox. (O), Cat. 3: Acute Toxicity (Oral), Category 3
 Eye Irr., Cat. 2: Eye Irritation, Category 2
 Oxid. Sol., Cat. 3: Oxidizing Solids, Category 3
 Skin Corr., Cat. 1A: Skin Corrosion, Category 1A
 Skin Irr., Cat. 2: Skin Irritation, Category 2
 H272: May intensify fire; oxidizer.
 H301: Toxic if swallowed.
 H314: Causes severe skin burns and eye damage.
 H315: Causes skin irritation.
 H319: Causes serious eye irritation.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 06/23/2014 SDS. Revised: **Section 1:**
Section 2: EMERGENCY OVERVIEW - IMMEDIATE
 CONCERNS. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT -

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SKIN. **Section 10:** HAZARDOUS POLYMERIZATION, STABLE. **Section 11:** ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat) ACUTE. **Section 14:** AIR (ICAO/IATA) - SPECIAL PROVISIONS ROAD AND RAIL (ADR/RID) (PROPER SHIPPING NAME), VESSEL (IMO/IMDG) - SPECIAL PROVISIONS ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information. **Section 15:** SECTION 15: Regulatory information. **Section 16:** GENERAL STATEMENTS.

General statements

: N/A= Not Applicable

Manufacturer disclaimer

: FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and manufacturer's knowledge) believed to be accurate; however, the manufacturer, makes no warranty with respect to the accuracy of the information or the suitability of the recommendation and assumes no liability to any user thereof. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.