

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 02/14/2013

SDS No : 118-001.5

Date Revised : 05/18/2015

Revision No : 4

Ultrapak® E Epinephrine Knitted Cord - (All Sizes)**SECTION 1 : Identification of the substance/preparation and of the company/undertaking****1.1. Product identifier**

Product code : ED/19707, EE/19708, EF/19709, EG/19710
Product name : Ultrapak® E Epinephrine Knitted Cord - (All Sizes)
Product description : Epinephrine impregnated knitted displacement cord

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

Relevant identified uses : Professional Dental Displacement Cord with Epinephrine

1.3. Details of the supplier of the safety data sheet**Manufacturer**

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

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.

Danger symbols : T+

R phrases : R27/28, R52/53

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

Health : Acute Toxicity (Dermal), Category 3
 Acute Toxicity (Oral), Category 3

2.2. Label elements**Classification according to Directive 1999/45/EC**

Hazard pictogram(s) : T+



Very toxic

R&S statement(s) : R27/28: Very toxic in contact with skin and if swallowed.
 R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

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

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:

Skull and
crossbones**Signal Word**

: DANGER

Hazard statement(s)

: H301: Toxic if swallowed.
 H311: Toxic in contact with skin.
 H412: Harmful to aquatic life with long lasting effects.

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.
 P313: Get medical advice/attention.
 P362: Take off contaminated clothing.
 P302+P352: IF ON SKIN: Wash with plenty of soap and water.
 P301: IF SWALLOWED:
 P310: Immediately call a POISON CENTER or doctor/physician.
 P330: Rinse mouth.
 P331: Do NOT induce vomiting.

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**

: Toxic by inhalation, skin contact and ingestion.

Physical hazards

: Harmful to aquatic life with long lasting effects.

SECTION 3: Composition / information on ingredients**3.1. Substances**

Not Applicable

3.2. Mixtures

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Chemical Name	CAS	EINECS No.	Wt. %	Classification according to Directive 67/548/EEC	Classification according to Regulation (EC) No 1272/2008 [CLP]
DL-Epinephrine Hydrochloride	329-63-5	206-346-0	< 20	T+; R26/27/28; R52/53	Acute Tox. (O), Cat. 3; Skin Irr., Cat. 2; Eye Irr., Cat. 2; STOT SE, Cat. 3; H301; H311; H315; H319; H335

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** : Remove contaminated clothing. Wash with soap and water. Get medical attention.
- Following ingestion** : If swallowed, rinse mouth with water, Do NOT Induce Vomiting. Give victim a glass of water or milk. Call a physician or poison control center immediately. Never give anything by mouth to an unconscious person.
- 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 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 slight irritation.
- Skin** : Very Toxic in contact with skin.
- Ingestion** : Toxic if swallowed.
- Inhalation** : None expected for this product.

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

- Notes to physician** : Toxic if swallowed and in contact with skin.

SECTION 5: Fire fighting measures**5.1. Extinguishing media**

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Ultrapak® E Epinephrine Knitted Cord - (All Sizes)**Extinguishing media** : Please see Fire Fighting Equipment under Section 5.3.**5.2. Special hazards arising from the substance or mixture****Hazardous combustion products** : Combustion has the potential to generate toxic fumes of the following:
Hydrogen chloride, nitrogen oxides, carbon oxides.**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** : 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** : Not Applicable**Large spill** : Not Applicable**6.4. Reference to other sections****Reference to other sections** : Not Applicable**SECTION 7: Handling and storage****7.1. Precautions for safe handling****Handling** : Keep away from heat, sparks and flame.**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 Dental Displacement Cord with Epinephrine**SECTION 8: Exposure controls / personal protection****8.1. Control parameters****Control parameters** : Not Determined

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Eye/face protection	: Wear eye protection
Skin protection	: Wear suitable protective clothing and gloves.
Respiratory protection	: Not needed for normal use.

SECTION 9: Physical and chemical properties**9.1. Information on basic physical and chemical properties**

Physical state	: Cotton, knitted cord
Colour	: Size-Dependent
Odour	: None

9.2. Other information

Percent volatile	: Not Determined
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SECTION 10: Stability and reactivity**10.1. Reactivity**

Reactivity	: Stable
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10.2. Chemical stability

Chemical stability	: Stable when stored and handled under recommended conditions.
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10.3. Possibility of hazardous reactions

Hazardous polymerization	: None
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10.4. Conditions to avoid

Conditions to avoid	: None known.
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10.5. Incompatible materials

Incompatible materials	: Contact with ferric sulfate solutions may form black or blue precipitate.
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10.6. Hazardous decomposition products

Hazardous decomposition products	: None known.
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SECTION 11: Toxicological information**11.1. Information on toxicological effects****Acute**

Dermal LD₅₀	: Not Determined
Oral LD₅₀	: Not Determined
Inhalation LC₅₀	: Not Determined

SECTION 12: Ecological information**12.1. Toxicity**

Toxicity	: Water pollutant
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96-hour LC₅₀ : Not Determined
48-hour EC₅₀ : Not Determined
96-hour EC₅₀ : Not Determined
Notes : 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 readily degradable.

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

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 : Not Dangerous Goods

14.6. Special precautions for user

ADR - road : Not Dangerous Goods
RID - rail : Not Dangerous Goods
IMDG - sea : Not Dangerous Goods

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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 : US Medical Device(not sold in the EU)

15.2. Chemical safety assessment

Chemical safety assessment : Not Determined

Additional information : This product is not considered dangerous for transportation

SECTION 16: Other information

Relevant R-phrases and/or H-statements (number and full text) : R26/27/28: Very toxic by inhalation, in contact with skin and if swallowed.
 R52/53: Harmful to aquatic organisms, may cause long-term adverse effects in the aquatic environment.
 Acute Tox. (O), Cat. 3: Acute Toxicity (Oral), Category 3
 Eye Irr., Cat. 2: Eye Irritation, Category 2
 STOT SE, Cat. 3: Target Organ Toxicity (Single exposure), Category 3
 Skin Irr., Cat. 2: Skin Irritation, Category 2
 H301: Toxic if swallowed.
 H311: Toxic in contact with skin.
 H315: Causes skin irritation.
 H319: Causes serious eye irritation.
 H335: May cause respiratory irritation.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 02/14/2013 SDS. Revised: **Section 1:** GENERAL USE, PRODUCT CODE/ PART #. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS PHYSICAL HAZARDS. **Section 4:** EYES, INGESTION, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE (INGESTION, INHALATION, SKIN). **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** GENERAL PROCEDURES, WATER SPILL, . **Section 7:** SHELF LIFE, STORAGE, . **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - SKIN . **Section 9:** COLOR, PERCENT VOLATILE. **Section 10:** CONDITIONS TO AVOID, HAZARDOUS DECOMPOSITION PRODUCTS, HAZARDOUS POLYMERIZATION, STABILITY, STABLE. **Section 11:** ACUTE (ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat)). **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀, Notes), SECTION 12: Ecological information. **Section 14:** AIR (ICAO/IATA) - SPECIAL PROVISIONS ROAD AND RAIL (ADR/RID), ROAD AND RAIL

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(ADR/RID) (PROPER SHIPPING NAME, UN NUMBER, PACKING GROUP), VESSEL (IMO/IMDG) (SPECIAL PROVISIONS), ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information. **Section 15:** RoHS, 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.