

# SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 3/20/2013

SDS No : 189-001.4

Date Revised : 2/27/2015

Revision No : 3

## Ultrapak® Dental Retraction Cord (All Sizes)

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

#### 1.1. Product identifier

**Product code** : 15315,19801,19802,19803,19804, 10285  
**Product name** : Ultrapak® Dental Retraction Cord (All Sizes)  
**Product description** : Knitted displacement cord

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

**Relevant identified uses** : Professional Dental Retraction Cord

#### 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**

: Not Applicable

#### 2.2. Label elements

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

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

#### 2.3. Other hazards

**Immediate concerns** : None known.

### 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
cotton	N/A	NA	100	Not classified

**SECTION 4: First aid measures****4.1. Description of first aid measures**

- Following eyes** : None  
**Following skin** : None  
**Following ingestion** : None  
**Following inhalation** : None

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

- Eyes** : None expected for this product.  
**Skin** : None expected for this product.  
**Ingestion** : None expected for this product.  
**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**

- Hazardous combustion products** : None known.  
**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 (CO<sub>2</sub>).

**SECTION 6: Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures**

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

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**Ultrapak® Dental Retraction Cord (All Sizes)****6.2. Environmental precautions****Water spill** : Not Applicable**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**SECTION 8: Exposure controls / personal protection****8.1. Control parameters****Control parameters** : Not Determined**8.2. Exposure controls****Eye/face protection** : Not Applicable**Skin protection** : Not Applicable**Respiratory protection** : Not Applicable**SECTION 9: Physical and chemical properties****9.1. Information on basic physical and chemical properties****Physical state** : Cotten, knitted cord**Colour** : Varied Colors**Odour** : None**9.2. Other information****Percent volatile** : 0**SECTION 10: Stability and reactivity****10.1. Reactivity****Reactivity** : Stable**10.2. Chemical stability**

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**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** : Not Determined

**10.5. Incompatible materials**

**Incompatible materials** : Not Applicable

**10.6. Hazardous decomposition products**

**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****Aquatic toxicity (acute)**

**96-hour LC<sub>50</sub>** : Not Determined

**48-hour EC<sub>50</sub>** : Not Determined

**96-hour EC<sub>50</sub>** : 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

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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

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**

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 5/7/2013 SDS. Revised: **Section 1:** GENERAL USE. **Section 2:** . **Section 4:** EYES, INGESTION, INHALATION, NOTES TO PHYSICIAN, SIGNS AND SYMPTOMS OF OVEREXPOSURE ( INGESTION, INHALATION, SKIN ), SKIN. **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** GENERAL PROCEDURES, WATER SPILL, . **Section 7:** SHELF LIFE, STORAGE, . **Section 8:** . **Section 9:** PERCENT VOLATILE. **Section 10:** CONDITIONS TO AVOID, HAZARDOUS DECOMPOSITION PRODUCTS, HAZARDOUS POLYMERIZATION, STABILITY, STABLE. **Section 11:**

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ACUTE. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE) ( 48-HOUR EC<sub>50</sub>, 96-HOUR EC<sub>50</sub> ), SECTION 12: Ecological information. **Section 14:** AIR (ICAO/IATA) - SPECIAL PROVISIONS ROAD AND RAIL (ADR/RID), ROAD AND RAIL (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:** GENERAL COMMENTS, RoHS, SECTION 15: Regulatory information.

**Manufacturer disclaimer**

: FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material MSDS(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.