

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 03/20/2013

SDS No : 189-001.5

Date Revised : 04/30/2015

Revision No : 5

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

: 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 : Not Classified

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)

Response : P270: Do not eat, drink or smoke when using this product.
 P314: Get medical advice/attention if you feel unwell.

Storage : P273: Avoid release to the environment.

Disposal : P501: Dispose of in compliance with governmental regulation.(EC 1975L0442-20/11/2003)

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2.3. Other hazards

Immediate concerns : None

SECTION 3: Composition / information on ingredients

3.1. Substances

Not Applicable

3.2. Mixtures

No Hazardous Components to Report, Made from 100% Cotton

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 (CO₂).

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

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

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Ultrapak® Dental Retraction Cord (All Sizes)**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** : 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 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 readily degradable.

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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 : 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

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Revision summary : This SDS replaces the 03/02/2015 SDS. Revised: **Section 1:** . **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS. **Section 3:** COMMENTS. **Section 14:** VESSEL (IMO/IMDG) - MARINE POLLUTANT #1.

Manufacturer disclaimer : FOR DENTAL USE ONLY: Use as directed. The information and recommendations are taken from sources (raw material SDS(s) and

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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.