

Safety Data Sheet
acc. to OSHA HCS

Printing date 11/29/2018

Reviewed on 10/24/2018

1 Identification

- **Product identifier**
- **Trade name:** *Ultrapak® E Epinephrine Knitted Cord (All Sizes)*
- **Article number:** 19707, 19708, 19709, 19710
- **Index number:** SDS 118-001.06
- **Application of the substance / the mixture** *Professional Dental Displacement Cord with Epinephrine*
- **Details of the supplier of the safety data sheet**
- **Manufacturer/Supplier:**
*Ultradent Products Inc.
505 W Ultradent Drive (10200 South)
South Jordan, UT 84095
Email : customerservice@ultradent.com
Phone: 1-888-230-1420*
- **Information department:** *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**



- Acute Tox. 4 H302 Harmful if swallowed.*
- Acute Tox. 4 H312 Harmful in contact with skin.*
- Skin Irrit. 2 H315 Causes skin irritation.*
- Eye Irrit. 2B H320 Causes eye irritation.*

- **Label elements**
- **GHS label elements**
Medical Devices are exempt from the labeling requirements of the Globally Harmonized System (GHS).
- **Hazard pictograms** GHS07
- **Signal word** *Warning*
- **Hazard-determining components of labeling:**
Epinephrine Hydrochloride
- **Hazard statements**
*Harmful if swallowed or in contact with skin.
Causes skin and eye irritation.*
- **Precautionary statements**
*If medical advice is needed, have product container or label at hand.
Keep out of reach of children.
Read label before use.
Wash thoroughly after handling.
Do not eat, drink or smoke when using this product.
Wear protective gloves / protective clothing.
If swallowed: Call a poison center/doctor if you feel unwell.
Rinse mouth.
If on skin: Wash with plenty of water.*

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Specific treatment (see on this label).

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

If skin irritation occurs: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

If eye irritation persists: Get medical advice/attention.

Dispose of contents/container in accordance with local/regional/national/international regulations.

· **Classification system:**

· **NFPA ratings (scale 0 - 4)**



· **HMIS-ratings (scale 0 - 4)**

HEALTH	2	Health = 2
FIRE	0	Fire = 0
REACTIVITY	0	Reactivity = 0

· **Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

3 Composition/information on ingredients

· **Chemical characterization: Mixtures**

· **Description:** Mixture of the substances listed below with nonhazardous additions.

· **Dangerous components:**

329-63-5	Epinephrine Hydrochloride	<30%
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4 First-aid measures

· **Description of first aid measures**

· **General information:**

Immediately remove any clothing soiled by the product.

Symptoms of poisoning may even occur after several hours; therefore medical observation for at least 48 hours after the accident.

· **After inhalation:** None

· **After skin contact:** Immediately wash with water and soap and rinse thoroughly.

· **After eye contact:**

Rinse opened eye for several minutes under running water. If symptoms persist, consult a doctor.

· **After swallowing:**

Get medical advice/attention immediately. Do not induce vomiting. Do not administer anything not explicitly authorised by a doctor.

· **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.

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5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:** Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **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:**
Dispose contaminated material as waste according to item 13.
- **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.
- **Protective Action Criteria for Chemicals**

· **PAC-1:**
None of the ingredients is listed.

· **PAC-2:**
None of the ingredients is listed.

· **PAC-3:**
None of the ingredients is listed.

7 Handling and storage

- **Handling:**
- **Precautions for safe handling**
No special precautions are necessary if used correctly.
See product labeling.
- **Information about protection against explosions and fires:** No special measures required.
- **Conditions for safe storage, including any incompatibilities**
- **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.
Keep receptacle tightly sealed.
- **Specific end use(s)** Professional Dental Displacement Cord with Epinephrine

8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see item 7.

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- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**
The product does not contain any relevant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:** *The lists that were valid during the creation were used as basis.*
- **Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**
*Keep away from foodstuffs, beverages and feed.
 Immediately remove all soiled and contaminated clothing.
 Wash hands before breaks and at the end of work.
 Avoid contact with the eyes and skin.*
- **Breathing equipment:** *Not required.*
- **Protection of hands:**



Protective gloves

*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 is based 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:** *Not required.*
- **Body protection:** *Protective work clothing*

9 Physical and chemical properties

· Information on basic physical and chemical properties

· General Information

· Appearance:

Form:	Knitted Cord
Color:	Various
Odor:	Odorless
Odor threshold:	Not determined.

· **pH-value:** Not applicable.

· Change in condition

Melting point/Melting range:	Not determined
Boiling point/Boiling range:	Not determined

· **Flash point:** Not applicable.

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· Flammability (solid, gaseous):	Not determined. Not applicable.
· Decomposition temperature:	Not determined.
· Auto igniting:	Product is not selfigniting.
· Danger of explosion:	Product does not present an explosion hazard.
· Explosion limits:	
Lower:	Not determined.
Upper:	Not determined.
· Vapor pressure:	Not applicable.
· Density:	Not determined.
· Relative density	Not determined.
· Vapor density	Not applicable.
· Evaporation rate	Not applicable.
· Solubility in / Miscibility with Water:	Insoluble
· Partition coefficient (n-octanol/water):	Not determined.
· Viscosity:	
Dynamic:	Not applicable.
Kinematic:	Not applicable.
· Solvent content:	
VOC content:	0.00 % 0.0 g/l / 0.00 lb/gal
Solids content:	100.0 %
· Other information	No further relevant information available.

10 Stability and reactivity

- **Reactivity** No further relevant information available.
- **Chemical stability**
- **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:**

· LD/LC50 values that are relevant for classification:		
ATE (Acute Toxicity Estimate)		
Oral	LD50	476-1,111 mg/kg
Dermal	LD50	1,429-3,333 mg/kg

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- **Primary irritant effect:**
- **on the skin:** Irritant to skin and mucous membranes.
- **on the eye:** Irritating effect.
- **Sensitization:** No sensitizing effects known.
- **Additional toxicological information:**
The product shows the following dangers according to internally approved calculation methods for preparations:
Harmful
Irritant
- **Carcinogenic categories**

· **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

· **NTP (National Toxicology Program)**

None of the ingredients is listed.

· **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

12 Ecological information

- **Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **Persistence and degradability** No further relevant information available.
- **Behavior 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 (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.

13 Disposal considerations

- **Waste treatment methods**
- **Recommendation:**
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
- **Uncleaned packagings:**
- **Recommendation:** Disposal must be made according to official regulations.
- **Recommended cleansing agent:** Water, if necessary with cleansing agents.

14 Transport information

- **UN-Number**
- **DOT, ADN, IMDG, IATA** not regulated

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- | | |
|---|------------------------|
| · UN proper shipping name | |
| · DOT, ADN, IMDG, IATA | <i>not regulated</i> |
| · Transport hazard class(es) | |
| · DOT, ADN, IMDG, IATA | |
| · Class | <i>not regulated</i> |
| · Packing group | |
| · DOT, IMDG, IATA | <i>not regulated</i> |
| · Environmental hazards: | <i>Not applicable.</i> |
| · Special precautions for user | <i>Not applicable.</i> |
| · Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code | <i>Not applicable.</i> |
| · UN "Model Regulation": | <i>not regulated</i> |

15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Sara**

· Section 355 (extremely hazardous substances):

None of the ingredients is listed.

· Section 313 (Specific toxic chemical listings):

None of the ingredients is listed.

· TSCA (Toxic Substances Control Act):

329-63-5 Epinephrine Hydrochloride

· TSCA new (21st Century Act) (Substances not listed)

329-63-5 Epinephrine Hydrochloride

· Proposition 65

· Chemicals known to cause cancer:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for females:

None of the ingredients is listed.

· Chemicals known to cause reproductive toxicity for males:

None of the ingredients is listed.

· Chemicals known to cause developmental toxicity:

None of the ingredients is listed.

· Carcinogenic categories

· EPA (Environmental Protection Agency)

None of the ingredients is listed.

· TLV (Threshold Limit Value established by ACGIH)

None of the ingredients is listed.

· NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

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- **GHS label elements**

Medical Devices are exempt from the labeling requirements of the Globally Harmonized System (GHS).

- **Hazard pictograms** GHS07

- **Signal word** Warning

- **Hazard-determining components of labeling:**

Epinephrine Hydrochloride

- **Hazard statements**

Harmful if swallowed or in contact with skin.

Causes skin and eye irritation.

- **Precautionary statements**

If medical advice is needed, have product container or label at hand.

Keep out of reach of children.

Read label before use.

Wash thoroughly after handling.

Do not eat, drink or smoke when using this product.

Wear protective gloves / protective clothing.

If swallowed: Call a poison center/doctor if you feel unwell.

Rinse mouth.

If on skin: Wash with plenty of water.

Specific treatment (see on this label).

If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do.

Continue rinsing.

If skin irritation occurs: Get medical advice/attention.

Take off contaminated clothing and wash it before reuse.

If eye irritation persists: Get medical advice/attention.

Dispose of contents/container in accordance with local/regional/national/international regulations.

- **Chemical safety assessment:**

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.

- **Department issuing SDS:** Regulatory Affairs

- **Contact:** Customer Service

- **Date of preparation / last revision** 11/29/2018 / -

- **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

IATA: International Air Transport Association

ACGIH: American Conference of Governmental Industrial Hygienists

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

VOC: Volatile Organic Compounds (USA, EU)

LC50: Lethal concentration, 50 percent

LD50: Lethal dose, 50 percent

PBT: Persistent, Bioaccumulative and Toxic

vPvB: very Persistent and very Bioaccumulative

NIOSH: National Institute for Occupational Safety

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Acute Tox. 4: Acute toxicity – Category 4

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Skin Irrit. 2: Skin corrosion/irritation – Category 2
Eye Irrit. 2B: Serious eye damage/eye irritation – Category 2B

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