

Date of issue: 06.10.2025 Revision: 06.10.2025

1 Identification

- Other means of identification
- · Trade name: UltrapakTM E Epinephrine Knitted Cord (All Sizes)
- · Article number: SDS 118-001.07R01, 19707, 19708, 19709, 19710, 198, 197, 199, 200
- · Relevant identified uses of the substance or mixture and uses advised against No further relevant information available.
- · 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 S)

South Jordan, UT 84095-3942

USA

onlineordersupport@ultradent.com

(800) 552-5512

Ultradent Australia Pty Ltd.

Level 22/2 Market Street

Sydney NSW 2000

Australia

 ${\it Email: info. anz@ultradent. com}$

Toll Free: 1-800-290929

- · Further information obtainable from: Customer Service
- · Emergency telephone number:

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

2 Hazard(s) Identification

· Classification of the substance or mixture



Acute toxicity - oral – Category 4 H302 Harmful if swallowed.

Acute toxicity - dermal - Category 4 H312 Harmful in contact with skin.

Skin corrosion/irritation - Category 2 H315 Causes skin irritation.

Eye damage/irritation – Category 2A H319 Causes serious eye irritation.

- · Label elements
- · GHS label elements Void
- · Hazard pictograms GHS07
- · Signal word Warning
- · Hazard-determining components of labelling:

Epinephrine Hydrochloride (>9-<20 %)

· Hazard statements

H302 Harmful if swallowed.

H312 Harmful in contact with skin.

H315 Causes skin irritation.

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H319 Causes serious eye irritation.

· Precautionary statements

P101 If medical advice is needed, have product container or label at hand.

P102 Keep out of reach of children.

P103 Read label before use.

P280 Wear protective gloves/protective clothing/eye protection/face protection. P301+P312 IF SWALLOWED: Call a POISON CENTER/doctor if you feel unwell.

P330 Rinse mouth.

P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if

present and easy to do. Continue rinsing.

P332+P313 If skin irritation occurs: Get medical advice/attention.

P501 Dispose of contents/container in accordance with local/regional/national/international

regulations.

3 Composition and Information on Ingredients

- · Chemical characterisation: Mixtures
- · Description: Mixture of substances listed below with nonhazardous additions.

Dangerous components:

329-63-5 Epinephrine Hydrochloride

>9-<20%

Acute toxicity - oral – Category 3, H301; Acute toxicity - dermal – Category 3, H311; Skin corrosion/irritation – Category 2, H315; Eye damage/irritation – Category 2A,

H31

· Additional information: For the wording of the listed hazard phrases refer to section 16.

4 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: In case of unconsciousness place patient stably in side position for transportation.
- · 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.

Call for a doctor immediately.

None

Void

- · Information for doctor: None
- · 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.

5 Fire Fighting Measures

- · Suitable extinguishing agents: Use fire extinguishing methods suitable to surrounding conditions.
- Special hazards arising from the substance or mixture No further relevant information available.

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· Protective equipment: No special measures required.

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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 section 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.

7 Handling and Storage

- · Handling:
- · Precautions for safe handling: See product labeling.
- · Information about fire and explosion protection: No special measures required.
- · 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 container tightly sealed.

· Specific end use(s) Professional Dental Displacement Cord with Epinephrine

8 Exposure controls and personal protection

- · Appropriate engineering controls No further data; see section 7.
- · Ingredients 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 valid during the making were used as basis.
- · 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.

- · Respiratory protection: 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 on consideration of the penetration times, rates of diffusion and the degradation (Contd. on page 4)

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· 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:



Tightly sealed goggles

· Body protection: Protective work clothing

9 Physical and Chemical Properties

· General Information

 $\cdot \textit{Appearance:}$

Form: Knitted Cord
Colour: Color Dependent
Odour: Odorless

• Odour threshold: Not determined. • pH-value: Not applicable.

· Change in condition

Melting point/freezing point:

 Initial boiling point and boiling range:
 Not determined

 Flash point:

 Flammability

 Decomposition temperature:

 Not determined

 Not determined
 Not determined

• Ignition temperature: Product is not selfigniting.

• Explosive properties: Product does not present an explosion hazard.

· Explosion limits:

Lower: Not determined.
Upper: Not determined.
Vapour pressure: Not applicable.
Density: Not determined.
Relative density Not determined.
Vapour 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.

· Other information

• Particle characteristics Not determined.

· Physical state Solid

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10 Stability and Reactivity

- · Reactivity No further relevant information available.
- 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

Harmful if swallowed.

Harmful in contact with skin.

LD/LC50 values relevant for classification:

ATE (Acute Toxicity Estimates)

Oral LD50 588-1,053 mg/kg
Dermal LD50 1,765-3,158 mg/kg

- · Primary irritant effect:
- · Skin corrosion/irritation Causes skin irritation.
- · Serious eye damage/irritation Causes serious eye irritation.
- · Respiratory or skin sensitisation Based on available data, the classification criteria are not met.
- · Germ cell mutagenicity Based on available data, the classification criteria are not met.
- · Carcinogenicity Based on available data, the classification criteria are not met.
- · Reproductive toxicity Based on available data, the classification criteria are not met.
- · STOT-single exposure Based on available data, the classification criteria are not met.
- · STOT-repeated exposure Based on available data, the classification criteria are not met.
- · Aspiration hazard Based on available data, the classification criteria are not met.

12 Ecological Information

- · Toxicity
- · Aquatic toxicity: No further relevant information available.
- · Persistence and degradability No further relevant information available.
- · Behaviour 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 (German Regulation) (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.

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13 Disposal considerations

- · Waste treatment methods
- · Recommendation

Dispose of contents/container in accordance with international, federal, state, and local regulations.

- · Uncleaned packaging:
- · Recommendation: Disposal must be made according to official regulations.

14 Transport injormation
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· ADG, IMDG, IATA

not regulated

· UN proper shipping name

· ADG, IMDG, IATA

not regulated

· Transport hazard class(es)

· ADG, ADN, IMDG, IATA

· Class not regulated

· Packing group

· ADG, IMDG, IATA

not regulated

· Environmental hazards:

Not applicable.

· Special precautions for user

Not Applicable

· Transport in bulk according to Annex II of Marpol

and the IBC Code

Not applicable.

· UN "Model Regulation":

not regulated

15 Regulatory information

- Safety, health and environmental regulations/legislation specific for the substance or mixture
- · NIOSH-Ca (National Institute for Occupational Safety and Health)

None of the ingredients is listed.

· Australian Inventory of Industrial Chemicals

None of the ingredients is listed.

· Standard for the Uniform Scheduling of Medicines and Poisons

None of the ingredients is listed.

· Australia: Priority Existing Chemicals

None of the ingredients is listed.

- · Directive 2012/18/EU
- · Named dangerous substances ANNEX I None of the ingredients is listed.
- · Chemical safety assessment:

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

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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.

· Relevant phrases from Section 3

H301 Toxic if swallowed.

H311 Toxic in contact with skin.

H315 Causes skin irritation.

H319 Causes serious eye irritation.

- · Department issuing SDS: Environmental, Health, and Safety
- · Contact: Customer Service
- · Abbreviations and acronyms:

ADR: Accord relatif au transport international des marchandises dangereuses par route (European Agreement Concerning the International

Carriage of Dangerous Goods by Road)

IMDG: International Maritime Code for Dangerous Goods

IATA: International Air Transport Association

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)

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

Acute toxicity - oral - Category 3: Acute toxicity - Category 3 Acute toxicity - oral - Category 4: Acute toxicity - Category 4

Skin corrosion/irritation – Category 2: Skin corrosion/irritation – Category 2

Eye damage/irritation - Category 2A: Serious eye damage/eye irritation - Category 2A