

# SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010  
Dental Use

**ULTRADENT**  
PRODUCTS, INC.

Date Issued : 03/01/2006  
SDS No : 32-001.7  
Date Revised : 09/23/2016  
Revision No : 6

## Ultradent® EDTA 18% Solution

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

#### 1.1. Product identifier

Product code : ET/66009  
Product name : Ultradent® EDTA 18% Solution  
Product description : Root canal chelating conditioner and cleanser

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

Relevant identified uses : Professional Dental Root Canal Cleansing & Conditioning Agent

#### 1.3. Details of the supplier of the safety data sheet

##### Manufacturer

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

##### EC Responsible Person

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 Regulation(EC) No 1272/2008 [CLP]

: The mixture has been assessed and/or tested for its physical, health and environmental hazards and the following classification applies.

**Health** : Acute Toxicity (Oral), Category 3  
Eye Irritation, Category 2A

#### 2.2. Label elements

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

Hazard pictogram(s) :



Exclamation  
mark

**Signal Word** : WARNING

**Hazard statement(s)** : H319: Causes serious eye irritation.  
H302: Harmful if swallowed.

##### Precautionary statement(s)

**Prevention** : P280: Wear protective gloves/protective clothing/eye protection/face protection.

**Response** : P305: IF IN EYES:

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P351: Rinse cautiously with water for several minutes.  
P337+P313: If eye irritation persists: Get medical advice/attention.  
P302+P352: IF ON SKIN: Wash with plenty of soap and water.  
P332+P313: If skin irritation occurs: Get medical advice/attention.  
P301: IF SWALLOWED:  
P331: Do NOT induce vomiting.  
P301+P312: IF SWALLOWED: Call a POISON CENTER or doctor/physician if you feel unwell.

**Storage** : P403+P235: Store in a well-ventilated place. Keep cool.  
P405: Store locked up.

**Disposal** : P501: Dispose of in compliance with governmental regulation. (EC1975L0442-20/11/2003)

### 2.3. Other hazards

Conclusion The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

## SECTION 3: Composition / information on ingredients

### 3.1. Substances

Not Applicable

### 3.2. Mixtures

Chemical Name	CAS	EINECS No.	Wt.%	Classification according to Regulation(EC) No 1272/2008 [CLP]
EDTA Tetrasodium Salt	64-02-8	200-573-9	< 20	Eye Irr.,Cat. 2A; H319

For full text of H-statements: see SECTION 16.

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

**Following eyes** : Immediately flush eyes with plenty of water. Get medical attention, if irritation persists.

**Following skin** : Wash with soap and water. Get medical attention if irritation develops or persists.

**Following ingestion** : Give large volumes of water. Do not induce vomiting. Consult a physician if you feel unwell.

**Following inhalation** : No specific treatment is necessary since this material is not likely to be hazardous by inhalation.

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

**Eyes** : Irritating to eyes.

**Skin** : May cause slight irritation.

**Ingestion** : Irritating to mouth, throat, and stomach.

**Inhalation** : None expected for this product.

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**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 : Foam, dry chemical, carbon dioxide (CO<sub>2</sub>).

**5.2. Special hazards arising from the substance or mixture**

Hazardous combustion products : None known.

**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.

**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 : Clean up spills immediately, observing precautions in Protective Equipment section.

Large Spill : Absorb with inert, damp non-combustible material, then flush area with water.

**6.4. Reference to other sections**

Reference to other sections : Not Applicable

**SECTION 7: Handling and storage**

**7.1. Precautions for safe handling**

Handling : Use suitable protective equipment.

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 Root Canal Cleansing & Conditioning Agent

**SECTION 8: Exposure controls / personal protection**

**8.1. Control parameters**

Control parameters : None

**8.2. Exposure controls**

Eye/face protection : Wear eye protection

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**Skin protection** : Wear suitable protective clothing and gloves.  
**Respiratory protection** : Good general ventilation should be sufficient to control airborne levels.

### SECTION 9: Physical and chemical properties

#### 9.1. Information on basic physical and chemical properties

**Physical state** : Low viscosity liquid  
**Appearance** : Clear  
**Colour** : Colorless  
**Odour** : Odorless or no characteristic odor  
**pH** : 10.9 - 11.1  
**Specific gravity** : 1.1 to 1.2

#### 9.2. Other information

**Percent volatile** : Not Volatile

### SECTION 10: Stability and reactivity

#### 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** : Strong acids, strong bases, and oxidizing agents.

#### 10.5. Incompatible materials

**Incompatible materials** : Not Determined

#### 10.6. Hazardous decomposition products

**Hazardous decomposition products** : Carbon dioxide, carbon monoxide, nitrogen oxides, sodium hydroxide, and ammonia

### SECTION 11: Toxicological information

#### 11.1. Information on toxicological effects

##### Acute

**Dermal LD<sub>50</sub>** : Not able to calculate ATE mix (dermal) due to lack of data on the components.

**Oral LD<sub>50</sub>** : > 150 mg/kg Mouse

**Inhalation LC<sub>50</sub>** : Not able to calculate ATE mix (inhalation) due to lack of data on the components.

**Other information** : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.

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**SECTION 12: Ecological information**

**12.1. Toxicity**

**Aquatic toxicity (acute)** : Do not allow to enter sewers or drains that may lead to waterways.

**12.2. Persistence and degradability**

**Persistence and degradability** : Not classified

**12.3. Bioaccumulative potential**

**Bioaccumulative potential** : Not classified

**12.4. Mobility in soil**

**Mobility in soil** : Not Available

**12.5. Results of PBT and vPvB assessment**

**Results of PBT and vPvB assessment** : Conclusion The substance does not fulfill the PBT and vPvB criteria for screening assessment; there are no indications of P or B properties.

**12.6. Other adverse effects**

**Environmental data** : Do not flush to sewer.

**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** : NAP

**14.2. UN proper shipping name**

**UN proper shipping name** : Not Dangerous Goods

**14.3. Transport hazard class(es)**

**Hazard classification** : NAP

**14.4. Packing group**

**Packing group** : NAP

**14.5. Environmental hazards**

**Marine pollutant #1** : NAP

**14.6. Special precautions for user**

**ADR - road** : NAP

**RID - rail** : NAP

**IMDG - sea** : NAP

**IATA - air** : NAP

**14.7. Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code**

**Transport in bulk** : NAP

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**SECTION 15: Regulatory information**

**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

**General comments** : Please refer to Medical Devices Directive 93/42/EEC.

**15.2. Chemical safety assessment**

**Chemical safety assessment** : See Section 11

**Additional information** : None of the ingredients are listed as a carcinogen by IARC, NTP, or CA Prop 65.  
This product is not considered dangerous for transportation.

**SECTION 16: Other information**

**Relevant H-statements (number and full text)** : Eye Irr., Cat. 2A: Eye Irritation, Category 2A  
H319: Causes serious eye irritation.

**Prepared by** : Anu Kattoju

**Revision summary** : This SDS replaces the 04/10/2015 SDS. Revised: **Section 1:** MSDS No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 4:** INGESTION, INHALATION. **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 6:** WATER SPILL. **Section 8:** . **Section 9:** pH, PHYSICAL STATE, SPECIFIC GRAVITY. **Section 11:** ACUTE ( INHALATION LC<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat) ACUTE, GENERAL COMMENTS. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, ENVIRONMENTAL DATA, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), AQUATIC TOXICITY (ACUTE) ( 48-HOUR EC<sub>50</sub>, 96-HOUR EC<sub>50</sub> ), SECTION 12: Ecological information. **Section 14:** ROAD AND RAIL (ADR/RID), VESSEL (IMO/IMDG) - MARINE POLLUTANT #1 ROAD AND RAIL (UK only) (CDG) - SPECIAL PROVISIONS SECTION 14: Transport information, UN number, Packing group, ADR - road, IMDG - sea, IATA - air. **Section 15:** COMMENTS, GENERAL COMMENTS, RoHS. **Section 16:** GENERAL STATEMENTS.

**General statements** : NAP = Not Applicable  
NE = Not Established  
TLV = Threshold Limit Value  
PEL = Permissible exposure limits  
MAK = Maximum Workplace Concentration  
STEL = Short-term exposure limit  
STEV = Short-term exposure value  
TWA = Time Weighted Average  
PPE = Personal Protective Equipment

**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.

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Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.