

# SAFETY DATA SHEET

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

**ULTRADENT**  
PRODUCTS, INC.

Date Issued : 08/27/2012  
SDS No : 21-001.8  
Date Revised : 09/14/2016  
Revision No : 7

**File-Eze®**

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

### 1.1. Product identifier

**Product code** : FE/10353  
**Product name** : File-Eze®  
**Product description** : Endodontic chelator and file lubricant

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

**Relevant identified uses** : Professional Endodontic File Lubricant

### 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 Directive 1999/45/EC

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

**Danger symbols** : Xi

**R phrases** : R36/38

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

**Health** : Acute Toxicity (Inhalation), Category 4  
Eye Irritation, Category 2B

### 2.2. Label elements

#### Classification according to Directive 1999/45/EC

**Hazard pictogram(s)** : Xi



Irritant

**R& statement(s)** : R36/38: Irritating to eyes and skin.

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


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<b>Hazard pictogram(s)</b>	:	 Exclamation mark
<b>Signal Word</b>	:	WARNING
<b>Hazard statement(s)</b>	:	H319: Causes serious eye irritation. H335: May cause respiratory irritation.
<b>Precautionary statement(s)</b>	:	
<b>Prevention</b>	:	P280: Wear protective gloves/protective clothing/eye protection/face protection.
<b>Response</b>	:	P305: IF IN EYES: 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. P285: In case of inadequate ventilation wear respiratory protection.
<b>Storage</b>	:	P103: Read label before use.
<b>Disposal</b>	:	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 Directive 67/548/EEC	Classification according to Regulation(EC) No 1272/2008 [CLP]
EDTA Tetrasodium Salt	64-02-8	200-573-9	19	Xi; R36/37/38	Eye Irr.,Cat. 2A; H319
Urea	57-13-6	200-315-5	< 15	Xi; R36/37/38	Eye Irr.,Cat. 2B; H319

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

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

<b>Following eyes</b>	:	Immediately flush eyes with plenty of water. Get medical attention, if irritation persists.
<b>Following skin</b>	:	Wash with soap and water. Get medical attention if irritation develops or persists.

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**Following ingestion** : If swallowed in small quantity the product is harmless, otherwise consult a doctor.

**Following inhalation** : Remove to fresh air and ventilate the contaminated area. Give oxygen or artificial respiration if needed.

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

**Eyes** : Irritating to eyes.  
**Skin** : May cause slight irritation.  
**Ingestion** : None expected for this product.  
**Inhalation** : May cause irritation.

**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** : Not Available

**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** : Not Applicable

**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

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**7.3. Specific end use(s)**

**Specific end use(s)** : Professional Endodontic File Lubricant

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

**8.1. Control parameters**

**Control parameters** : Urea CAS: 57-13-6

AIHA WHEEL
10 mg/m3 TWA

**8.2. Exposure controls**

**Eye/face protection** : Wear eye protection

**Skin protection** : Wear suitable protective clothing and gloves.

**Respiratory protection** : Good general ventilation should be sufficient to control airborne levels. In case of insufficient ventilation, wear suitable respiratory equipment.

**SECTION 9: Physical and chemical properties**

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

**Physical state** : Gel  
**Colour** : White  
**Odour** : Odorless or no characteristic odor  
**pH** : 9.5 to 10.3  
**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** : Strong acids, strong bases, and oxidizing agents.

**10.6. Hazardous decomposition products**

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**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>** : > 50000 mg/kg Rabbit/Hamster

**Notes** : ~29% of the mixture consists of components of unknown toxicity (Dermal).

**Oral LD<sub>50</sub>** : > 7600 mg/kg Rat

**Notes** : There are no components of unknown toxicity (oral).

**Inhalation LC<sub>50</sub>** : > 2 mg/L/4H Rat

**Notes** : ~29% of the mixture consists of components of unknown toxicity (Inhalation).

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

### SECTION 12: Ecological information

#### 12.1. Toxicity

**Aquatic toxicity (acute)** : Not Established

#### 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** : No data available.

### 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

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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 : Not Dangerous Goods

### 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

## 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 R-phrases and/or H-statements (number and full text) : R36/37/38: Irritating to eyes, respiratory system and skin.  
Eye Irr., Cat. 2A: Eye Irritation, Category 2A  
Eye Irr., Cat. 2B: Eye Irritation, Category 2B  
H319: Causes serious eye irritation.

Prepared by : Anu Kattoju

Revision summary : This SDS replaces the 03/24/2015 SDS. Revised: **Section 1:** MSDS No. **Section 2:** EMERGENCY OVERVIEW - IMMEDIATE CONCERNS 2.3. Other hazards. **Section 4:** INHALATION, SIGNS AND SYMPTOMS OF OVEREXPOSURE - INHALATION. **Section 5:** EXPLOSION HAZARDS, EXTINGUISHING MEDIA, FIRE EXPLOSION, FIRE FIGHTING EQUIPMENT, HAZARDOUS COMBUSTION PRODUCTS, SENSITIVE TO STATIC DISCHARGE, SENSITIVITY TO IMPACT. **Section 8:** PERSONAL PROTECTIVE EQUIPMENT - RESPIRATORY . **Section 9:** SPECIFIC GRAVITY. **Section 11:** ACUTE ( DERMAL LD<sub>50</sub> (rabbit), DERMAL LD<sub>50</sub> (rabbit), DERMAL LD<sub>50</sub> (rabbit), ORAL LD<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat), INHALATION LC<sub>50</sub> (rat), INHALATION LC<sub>50</sub>

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(rat), INHALATION LC<sub>50</sub> (rat), ORAL LD<sub>50</sub> (rat) ACUTE, GENERAL COMMENTS. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, 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), 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 = Permittable 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. Each user should review these recommendations in the specific context of the intended use and determine whether they are appropriate.