

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



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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Hazard pictogram(s)	: 
	Exclamation mark
Signal Word	: WARNING
Hazard statement(s)	: H319: Causes serious eye irritation. H335: May cause respiratory irritation.
Precautionary statement(s)	
Prevention	: P280: Wear protective gloves/protective clothing/eye protection/face protection.
Response	: 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.
Storage	: P103: Read label before use.
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 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

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.

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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 (CO₂).

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 LD₅₀ : > 50000 mg/kg Rabbit/Hamster

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

Oral LD₅₀ : > 7600 mg/kg Rat

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

Inhalation LC₅₀ : > 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 LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), DERMAL LD₅₀ (rabbit), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat), ORAL LD₅₀ (rat), INHALATION LC₅₀ (rat), INHALATION LC₅₀

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(rat), INHALATION LC₅₀ (rat), ORAL LD₅₀ (rat) ACUTE, GENERAL COMMENTS. **Section 12:** CHEMICAL FATE INFORMATION, DISTRIBUTION, BIOACCUMULATION/ACCUMULATION, AQUATIC TOXICITY (ACUTE), AQUATIC TOXICITY (ACUTE) (48-HOUR EC₅₀, 96-HOUR EC₅₀), 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.