

SAFETY DATA SHEET

according to Regulation (EC) No. 453/2010

Dental Use



Date Issued : 08/27/2012

SDS No : 21-001.7

Date Revised : 03/24/2015

Revision No : 6

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

Distributor

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 : Eye Irritation
 Skin Irritation

2.2. Label elements**Classification according to Directive 1999/45/EC**

Hazard pictogram(s) : Xi



Irritant

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

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

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ULTRADENT
 PRODUCTS, INC.

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Hazard pictogram(s)



Exclamation
 mark

Signal Word

: WARNING

Hazard statement(s)

: H317: May cause an allergic skin reaction.

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.

Storage

: P103: Read label before use.

Disposal

: P501: Dispose of in compliance with governmental regulation. (EC 1975L0442-20/11/2003)

2.3. Other hazards

Immediate concerns

: No other adverse human effects.

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	H318; H302
Urea	57-13-6	200-315-5	< 15	Xi; R36/37/38	H302; H312; H317; H319; H334; H335; H351; H371; H413

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

SECTION 4: First aid measures

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File-Eze®**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** : If swallowed in small quantity the product is harmless, otherwise consult a doctor.
- Following inhalation** : No specific treatment is necessary since this material is not likely to be hazardous by inhalation. If exposed to excessive levels of dusts or fumes, remove to fresh air and get medical attention if cough or other symptoms develop.

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** : None expected for this product.

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** : Please see Fire Fighting Equipment under Section 5.3.

5.2. Special hazards arising from the substance or mixture

- Hazardous combustion products** : Not Determined
- Explosion hazards** : Not Determined
- Fire explosion** : Not Determined
- Sensitive to static discharge** : Not Determined
- Sensitivity to impact** : Not Determined

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.
- Fire fighting equipment** : Foam, dry chemical, carbon dioxide (CO₂).

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

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File-Eze®**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 Endodontic File Lubricant

SECTION 8: Exposure controls / personal protection**8.1. Control parameters**

- Control parameters** : Not Determined

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.

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

9.2. Other information

- Percent volatile** : Not Volatile

SECTION 10: Stability and reactivity**10.1. Reactivity**

- Reactivity** : Stable

10.2. Chemical stability

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File-Eze®**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****Hazardous decomposition products** : Carbon dioxide, carbon monoxide, nitrogen oxides, sodium hydroxide, and ammonia**SECTION 11: Toxicological information****11.1. Information on toxicological effects****Acute****Notes** : Device is biocompatible when used as directed by dental professionals per ISO 10993-1.**SECTION 12: Ecological information****12.1. Toxicity****Aquatic toxicity (acute)****96-hour LC₅₀** : Not Determined**48-hour EC₅₀** : Not Determined**96-hour EC₅₀** : Not Determined**12.2. Persistence and degradability****Persistence and degradability** : Not Determined**12.3. Bioaccumulative potential****Bioaccumulative potential** : Not Determined**12.4. Mobility in soil****Mobility in soil** : Not Determined**12.5. Results of PBT and vPvB assessment****Results of PBT and vPvB assessment** : Not Determined**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

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1975L0442-20/11/2003)

SECTION 14: Transport information**14.1. UN number**

UN number : N/A

14.2. UN proper shipping name

UN proper shipping name : Not Dangerous Goods

14.3. Transport hazard class(es)

Hazard classification : N/A

14.4. Packing group

Packing group : N/A

14.5. Environmental hazards

Marine pollutant #1 : Not Dangerous Goods

14.6. Special precautions for user

ADR - road : Not Dangerous Goods

RID - rail : Not Dangerous Goods

IMDG - sea : Not Dangerous Goods

IATA - air : Not Dangerous Goods

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

Transport in bulk : Not Dangerous Goods

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**

RoHS : Please refer to Medical Devices Directive 93/42/EEC

15.2. Chemical safety assessment

Chemical safety assessment : See Section 11

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.
 H302: Harmful if swallowed.
 H312: Harmful in contact with skin.
 H317: May cause an allergic skin reaction.
 H318: Causes serious eye damage.
 H319: Causes serious eye irritation.
 H334: May cause allergy or asthma symptoms or breathing difficulties if inhaled.
 H335: May cause respiratory irritation.
 H351: Suspected of causing cancer .
 H371: May cause damage to organs .
 H413: May cause long lasting harmful effects to aquatic life.

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Prepared by	: Anu Kattoju
Revision summary	: This SDS replaces the 01/29/2015 SDS. Revised: Section 1: . Section 2: . Section 9: PERCENT VOLATILE. Section 10: HAZARDOUS POLYMERIZATION, INCOMPATIBLE MATERIALS. Section 11: ACUTE (ORAL LD ₅₀ (rat), INHALATION LC ₅₀ (rat) ACUTE. Section 15: SECTION 15: Regulatory information.
General statements	: N/A= Not Applicable
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.