

## Safety Data Sheet

according to WHS Regulations

Printing date 28.07.2023

Revision: 28.07.2023

### 1 Identification

- **Product identifier**
- **Trade name:** File-Eze™
- **Article number:** SDS 21-001.09R02, 10353
- **Relevant identified uses of the substance or mixture and uses advised against**  
Professional Endodontic File Lubricant
- **Application of the substance / the mixture** Professional Endodontic File Lubricant
- **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  
  
Ultradent Australia Pty Ltd.  
Level 22/2 Market Street  
Sydney NSW 2000  
Australia  
Email: info.anz@ultradent.com  
Toll Free: 1-800-290929
- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**  
CHEMTREC (NORTH AMERICA) : (800) 424-9300  
(INTERNATIONAL) : +(703) 527-3887

### 2 Hazard(s) Identification

- **Classification of the substance or mixture**



Acute Tox. 4	H332 Harmful if inhaled.
Skin Irrit. 2	H315 Causes skin irritation.
Serious eye damage/irritation – Category 2A H319 Causes serious eye irritation.	

- **Label elements**
- **GHS label elements** Void
- **Hazard pictograms** GHS07
- **Signal word** Warning
- **Hazard statements**  
H332 Harmful if inhaled.  
H315 Causes skin irritation.  
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.

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- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
 P280 Wear eye protection / face protection.  
 P304+P340 IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.  
 P305+P351+P338 IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
 P312 Call a POISON CENTER/doctor if you feel unwell.  
 P321 Specific treatment (see on this label).

### 3 Composition and Information on Ingredients

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

- **Dangerous components:**

10378-23-1	EDTA Tetrasodium Salt	≥10-<20%
	⚠ Skin Irrit. 2, H315; Serious eye damage/irritation – Category 2A, H319; STOT SE 3, H335	
57-13-6	Urea	10-<30%
	⚠ Serious eye damage/irritation – Category 2A, H319	
13463-67-7	Titanium Dioxide	≥0.1-<10%
	⚠ Carc. 2, H351	

- **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:**  
 This product is a viscous gel, therefore chance of inhalation is extremely low.  
 Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.  
 In case of unconsciousness place patient stably in side position for transportation.
- **After skin contact:**  
 If skin irritation continues, consult a doctor.  
 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:** If swallowed in large quantities seek medical attention.
- **Information for doctor:**
- **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:**  
 Foam, dry chemical, carbon dioxide  
 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:**  
Wear fully protective suit.  
Mouth respiratory protective device.

### 6 Accidental Release Measures

- **Personal precautions, protective equipment and emergency procedures** Ensure adequate ventilation
- **Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).  
Ensure adequate ventilation.
- **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:**  
Ensure good ventilation/exhaustion at the workplace.  
Prevent formation of aerosols.
- **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 Endodontic File Lubricant

### 8 Exposure controls and personal protection

- **Additional information about design of technical facilities:** No further data; see item 7.

- **Ingredients with limit values that require monitoring at the workplace:**

13463-67-7 Titanium Dioxide

WES	Long-term value: 10 mg/m <sup>3</sup> inhalable dust
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- **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:**  
In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use self-contained respiratory protective device.

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**· 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

**· 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****· Appearance:****· Form:**

Gel

**· Colour:**

White

**· Odour:**

Characteristic

**· Odour threshold:**

Not determined.

**· pH-value at 20 °C:**

9.5-10.3

**· Change in condition****· Melting point/freezing point:**

Undetermined.

**· Initial boiling point and boiling range:**

Undetermined.

**· Flash point:**

218 °C

**· Flammability (solid, gas):**

Not applicable.

**· Decomposition temperature:**

Not determined.

**· Auto-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 determined.

**· Density at 20 °C:**1.2 g/cm<sup>3</sup>**· Relative density**

Not determined.

**· Vapour density**

Not determined.

**· Evaporation rate**

Not determined.

**· Solubility in / Miscibility with****· water:**

Dispersible.

**· Partition coefficient: n-octanol/water:**

Not determined.

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- |                            |  |
|----------------------------|--|
| <b>· Viscosity:</b>        |  |
| <b>· Dynamic:</b>          | Not determined.                            |
| <b>· Kinematic:</b>        | Not determined.                            |
| <b>· Other information</b> | No further relevant information available. |

### 10 Stability and Reactivity

- **Reactivity** Stable
- **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:**
  - Oxidizing agents
  - Alkalies
  - Acids
- **Hazardous decomposition products:**
  - Sodium Hydroxide
  - Nitrogen oxides
  - Ammonia
  - Carbon monoxide and carbon dioxide

### 11 Toxicological Information

- **Information on toxicological effects**
- **Acute toxicity** Harmful if inhaled.

#### · LD/LC50 values relevant for classification:

##### 57-13-6 Urea

Oral	LD50	8,471 mg/kg (rat)
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##### 13463-67-7 Titanium Dioxide

Oral	LD50	>5,000 mg/kg (rat)
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Dermal	LD50	>5,000 mg/kg (rabbit)
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- **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:

##### 13463-67-7 Titanium Dioxide

EC50	>100 mg/kg (Algae)
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&gt;1,000 mg/kg (Fish)

- **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.

### 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 information

- |   |                 |
|---|-----------------|
| · <b>UN-Number</b>  |                 |
| · <b>ADG, ADN, IMDG, IATA</b>   | not regulated   |
| · <b>UN proper shipping name</b>  |                 |
| · <b>ADG, ADN, IMDG, IATA</b>   | not regulated   |
| · <b>Transport hazard class(es)</b>   |                 |
| · <b>ADG, ADN, IMDG, IATA</b>   |                 |
| · <b>Class</b>  | not regulated   |
| · <b>Packing group</b>  |                 |
| · <b>ADG, IMDG, IATA</b>  | not regulated   |
| · <b>Environmental hazards:</b>   | Not applicable. |
| · <b>Special precautions for user</b>                                       | Not Applicable  |
| · <b>Transport in bulk according to Annex II of Marpol and the IBC Code</b> | Not applicable. |
| · <b>UN "Model Regulation":</b>   | not regulated   |

### 15 Regulatory information

- **Safety, health and environmental regulations/legislation specific for the substance or mixture**
- **Australian Inventory of Industrial Chemicals**  
*All ingredients are listed.*

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· **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

### 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**

H315 Causes skin irritation.

H319 Causes serious eye irritation.

H335 May cause respiratory irritation.

H351 Suspected of causing cancer.

· **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

Acute Tox. 4: Acute toxicity – Category 4

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

Serious eye damage/irritation – Category 2A: Serious eye damage/eye irritation – Category 2A

Carc. 2: Carcinogenicity – Category 2

STOT SE 3: Specific target organ toxicity (single exposure) – Category 3

· **\* Data compared to the previous version altered.**

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