

## Safety data sheet according to UK REACH

Printing date 05.02.2025

Version number 1

Revision: 05.02.2025

### 1 Identification of the substance/mixture and of the company/undertaking

- **Product identifier**
- **Trade name:** File-Eze™
- **Article number:** SDS 21-001.10R01, 10353, 10305, 10693, 682
- **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
  
- 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
- **Further information obtainable from:** Customer Service
- **Emergency telephone number:**  
CHEMTREC (NORTH AMERICA) : (800) 424-9300  
(INTERNATIONAL) : +(703) 527-3887

### 2 Hazards identification

- **Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008**



Acute Tox. 4 H332 Harmful if inhaled.  
Skin Irrit. 2 H315 Causes skin irritation.  
Eye Irrit. 2 H319 Causes serious eye irritation.

- **Label elements**
- **Labelling according to Regulation (EC) No 1272/2008** 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 carefully and follow all instructions.

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- P261 Avoid breathing dust/fume/gas/mist/vapours/spray.  
 P280 Wear protective gloves / eye protection / face protection.  
 P304+P340 IF INHALED: Remove person to fresh air and keep 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/information on ingredients

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

- **Dangerous components:**

CAS: 10378-23-1	EDTA Tetrasodium Salt	>10-<20%
EC number: 600-485-4	⚠ Skin Irrit. 2, H315; Eye Irrit. 2, H319; STOT SE 3, H335	
CAS: 13463-67-7	Titanium Dioxide	<1%
EINECS: 236-675-5	⚠ Carc. 2, H351	

- **Additional information:** For the wording of the listed hazard phrases refer to section 16.

### 4 First aid measures

- **Description of 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.
- **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 Firefighting measures

- **Extinguishing media**
- **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.
- **Advice for firefighters:**
- **Protective equipment:**  
Wear fully protective suit.

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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

- **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.
- **Conditions for safe storage, including any incompatibilities**
- **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/personal protection

- **Control parameters**

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

### 13463-67-7 Titanium Dioxide

WEL Long-term value: 10\* 4\*\* mg/m<sup>3</sup>

\*total inhalable \*\*respirable

- **Additional information:** The lists valid during the making were used as basis.
- **Exposure controls**
- **Appropriate engineering controls** No further data; see section 7.
- **Individual protection measures, such as 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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### · Hand protection



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/face protection



Tightly sealed goggles

### · Body protection: Protective work clothing

## 9 Physical and chemical properties

### · Information on basic physical and chemical properties

#### · General Information

· Physical state	Fluid
· Colour:	White
· Odour:	Characteristic
· Odour threshold:	Not determined.
· Melting point/freezing point:	Undetermined.
· Boiling point or initial boiling point and boiling range	Undetermined.
· Flammability	Not applicable.
· Lower and upper explosion limit	
· Lower:	Not determined.
· Upper:	Not determined.
· Flash point:	218 °C
· Decomposition temperature:	Not determined.
· pH at 20 °C	9.5-10.3
· Viscosity:	
· Kinematic viscosity	Not determined.
· Dynamic:	Not determined.
· Solubility	
· water:	Dispersible.
· Partition coefficient n-octanol/water (log value)	Not determined.
· Vapour pressure:	Not determined.
· Density and/or relative density	
· Density at 20 °C:	1.2 g/cm <sup>3</sup>
· Relative density	Not determined.
· Vapour density	Not determined.

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- **Other information**
  - **Appearance:**
  - **Form:** Gel
  - **Important information on protection of health and environment, and on safety.**
  - **Ignition temperature:** Product is not selfigniting.
  - **Explosive properties:** Product does not present an explosion hazard.
  - **Change in condition**
  - **Evaporation rate** Not determined.
- 
- **Information with regard to physical hazard classes**
  - **Explosives** Void
  - **Flammable gases** Void
  - **Aerosols** Void
  - **Oxidising gases** Void
  - **Gases under pressure** Void
  - **Flammable liquids** Void
  - **Flammable solids** Void
  - **Self-reactive substances and mixtures** Void
  - **Pyrophoric liquids** Void
  - **Pyrophoric solids** Void
  - **Self-heating substances and mixtures** Void
  - **Substances and mixtures, which emit flammable gases in contact with water** Void
  - **Oxidising liquids** Void
  - **Oxidising solids** Void
  - **Organic peroxides** Void
  - **Corrosive to metals** Void
  - **Desensitised explosives** Void

### 10 Stability and reactivity

- **Reactivity** Stable
- **Chemical stability**
- **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
  - Alkalis
  - Acids
- **Hazardous decomposition products:**
  - Sodium Hydroxide
  - Nitrogen oxides
  - Ammonia
  - Carbon monoxide and carbon dioxide

### 11 Toxicological information

- **Information on hazard classes as defined in Regulation (EC) No 1272/2008**
- **Acute toxicity** Harmful if inhaled.

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

**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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· **Primary irritant effect:**

· **Skin corrosion/irritation** Causes skin irritation.

· **Serious eye damage/irritation** Causes serious eye irritation.

· **Information on other hazards**

· **Endocrine disrupting properties**

None of the ingredients is listed.

### 12 Ecological information

· **Toxicity**

· **Aquatic toxicity:**

**13463-67-7 Titanium Dioxide**

EC50	>100 mg/kg (Algae)
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	>1,000 mg/kg (Fish)
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· **Persistence and degradability** No further relevant information available.

· **Bioaccumulative potential** No further relevant information available.

· **Mobility in soil** No further relevant information available.

· **Results of PBT and vPvB assessment**

· **PBT:** Not applicable.

· **vPvB:** Not applicable.

· **Endocrine disrupting properties** The product does not contain substances with endocrine disrupting properties.

· **Other adverse effects**

· **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.

### 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

· **UN number or ID number**

· **ADR, ADN, IMDG, IATA** not regulated

· **UN proper shipping name**

· **ADR, ADN, IMDG, IATA** not regulated

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- |  |                 |
|--|-----------------|
| <b>· Transport hazard class(es)</b>                              |                 |
| <b>· ADR, ADN, IMDG, IATA</b>                                    |                 |
| <b>· Class</b>   | not regulated   |
| <b>· Packing group</b>   |                 |
| <b>· ADR, IMDG, IATA</b>   | not regulated   |
| <b>· Environmental hazards:</b>                                  | Not applicable. |
| <b>· Special precautions for user</b>                            | Not Applicable  |
| <b>· Maritime transport in bulk according to IMO instruments</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**

- **NIOSH-Ca (National Institute for Occupational Safety and Health)**

None of the ingredients is listed.

- **Poisons Act**

- **Regulated explosives precursors**

None of the ingredients is listed.

- **Regulated poisons**

None of the ingredients is listed.

- **Reportable explosives precursors**

None of the ingredients is listed.

- **Reportable poisons**

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

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*IATA: International Air Transport Association**GHS: Globally Harmonised System of Classification and Labelling of Chemicals**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**NIOSH: National Institute for Occupational Safety**ATE: Acute toxicity estimate values**Acute Tox. 4: Acute toxicity – Category 4**Skin Irrit. 2: Skin corrosion/irritation – Category 2**Eye Irrit. 2: Serious eye damage/eye irritation – Category 2**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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