



# Safety Data Sheet

acc. to OSHA HCS

Printing date 01/22/2025

Reviewed on 12/11/2024

## 1 Identification

- **Product identifier**
- **Trade name:** File-Eze™
- **Article number:** SDS 21-001.10R01, 10353, 10305, 10693, 682
- **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
- **Information department:** 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 Toxicity - Inhalation 4 H332 Harmful if inhaled.  
 Skin Irritation 2 H315 Causes skin irritation.  
 Eye Irritation 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**  
P261 Avoid breathing dust/fume/gas/mist/vapors/spray  
P264 Wash thoroughly after handling.  
P271 Use only outdoors or in a well-ventilated area.  
P280 Wear protective gloves / eye protection / face protection.  
P302+P352 If on skin: Wash with plenty of water.  
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).  
P362+P364 Take off contaminated clothing and wash it before reuse.  
P332+P313 If skin irritation occurs: Get medical advice/attention.  
P337+P313 If eye irritation persists: Get medical advice/attention.

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- **Classification system:**
- **NFPA ratings (scale 0 - 4)**



- **HMIS-ratings (scale 0 - 4)**

HEALTH	2	Health = 2
FIRE	1	Fire = 1
REACTIVITY	0	Reactivity = 0

### 3 Composition/information on ingredients

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

- **Dangerous components:**

10378-23-1	EDTA Tetrasodium Salt	>10-<20%
25322-68-3	Polyethylene Glycol	>10-≤25%
57-13-6	Urea	>10-≤25%
	Trade Secret	1-10%

- **Additional information:**

The specific chemical identity of composition is being withheld as a trade secret. The specific chemical identity is made available to health professionals, employees, and designated representatives in accordance with the applicable provisions of paragraph §1910.1200.

### 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.
- **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.

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## 5 Fire-fighting measures

- **Extinguishing media**
- **Suitable extinguishing agents:**  
Foam, dry chemical, carbon dioxide  
Use fire fighting measures that suit the environment.
- **Special hazards arising from the substance or mixture** No further relevant information available.
- **Advice for firefighters**
- **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 protection against explosions and fires:** 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 receptacle tightly sealed.
- **Specific end use(s)** Professional Endodontic File Lubricant

## 8 Exposure controls/personal protection

- **Additional information about design of technical systems:** No further data; see section 7.
- **Control parameters**
- **Components with limit values that require monitoring at the workplace:**  
The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit.  
At this time, the remaining constituent has no known exposure limits.

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**25322-68-3 Polyethylene Glycol**

WEEL Long-term value: 10 mg/m<sup>3</sup>  
(H); MW>200

**57-13-6 Urea**

WEEL Long-term value: 10 mg/m<sup>3</sup>

**Trade Secret**

TWA Short-term value: 0.8 mg/m<sup>3</sup>

· **Additional information:** The lists that were valid during the creation were used as basis.

· **Exposure controls**

· **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.

· **Breathing equipment:**

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

· **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 is based 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

· **Information on basic physical and chemical properties**

· **General Information**

· **Appearance:**

**Form:** Gel  
**Color:** White

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· <b>Odor:</b>	Characteristic
· <b>Odor threshold:</b>	Not determined.
· <b>pH-value at 20 °C:</b>	9.5-10.3
· <b>Change in condition</b>	
<b>Melting point/Melting range:</b>	Undetermined.
<b>Boiling point/Boiling range:</b>	Undetermined
· <b>Flash point:</b>	218 °C
· <b>Flammability:</b>	Not applicable.
· <b>Decomposition temperature:</b>	Not determined.
· <b>Ignition temperature:</b>	Product is not selfigniting.
· <b>Danger of explosion:</b>	Product does not present an explosion hazard.
· <b>Explosion limits:</b>	
<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
· <b>Vapor pressure:</b>	Not determined.
· <b>Density at 20 °C:</b>	1.2 g/cm <sup>3</sup>
· <b>Relative density</b>	Not determined
· <b>Vapor density</b>	Not determined.
· <b>Evaporation rate</b>	Not determined.
· <b>Solubility in / Miscibility with Water:</b>	Dispersible.
· <b>Partition coefficient (n-octanol/water):</b>	Not determined.
· <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**
- **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

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## 11 Toxicological information

- **Information on toxicological effects**

- **Acute toxicity:**

- **LD/LC50 values that are relevant for classification:**

### 25322-68-3 Polyethylene Glycol

Oral	LD50	19,600 mg/kg (guinea pig) 17,300 mg/kg (mouse) >10,000 mg/kg (rat)
Dermal	LC50 Fish	>100 mg/l (Fish)
	LD50	>20,000 mg/kg (rabbit)
	LC50(Daphnia magna)	>10,000 mg/l (Water Flea) (Toxicity to aquatic invertebrates)

### 57-13-6 Urea

Oral	LD50	8,471 mg/kg (rat)
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### Trade Secret

Oral	LD50	>15,000 mg/kg (mouse) >3,300 mg/kg (rat)
Dermal	LC50 Fish	>10,000 mg/l (Fish) (Toxicity to fish)
	LD50	>5,000 mg/kg (rabbit)
	Inhalative LC50/4 h	0.139 mg/l (rat)

- **Primary irritant effect:**

- **on the skin:** Irritant to skin and mucous membranes.

- **on the eye:** Irritating effect.

- **Sensitization:** No sensitizing effects known.

- **Additional toxicological information:**

The product shows the following dangers according to internally approved calculation methods for preparations:

Harmful

Irritant

- **Carcinogenic categories**

- **IARC (International Agency for Research on Cancer)**

None of the ingredients is listed.

- **NTP (National Toxicology Program)**

None of the ingredients is listed.

- **OSHA-Ca (Occupational Safety & Health Administration)**

None of the ingredients is listed.

## 12 Ecological information

- **Toxicity**

- **Aquatic toxicity:**

### Trade Secret

EC50 >1,000 mg/kg (daphnia)

- **Persistence and degradability** No further relevant information available.

- **Behavior in environmental systems:**

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

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- **Mobility in soil** No further relevant information available.
- **Additional ecological information:**
- **General notes:**  
Water hazard class 1 (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 packagings:**
- **Recommendation:** Disposal must be made according to official regulations.

## 14 Transport information

- |                                                                                  |                 |
|----------------------------------------------------------------------------------|-----------------|
| · <b>UN-Number</b>                                                               | Not Regulated   |
| · <b>DOT, ADN, IMDG, IATA</b>                                                    | Not Regulated   |
| · <b>UN proper shipping name</b>                                                 | Not Regulated   |
| · <b>DOT, ADN, IMDG, IATA</b>                                                    | Not Regulated   |
| · <b>Transport hazard class(es)</b>                                              | Not Regulated   |
| · <b>DOT, ADN, IMDG, IATA</b>                                                    | Not Regulated   |
| · <b>Class</b>                                                                   | Not Regulated   |
| · <b>Packing group</b>                                                           | Not Regulated   |
| · <b>DOT, 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 MARPOL73/78 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**  
No further relevant information available.
- **Sara**
- **Section 355 (extremely hazardous substances):**  
None of the ingredients is listed.
- **Section 313 (Specific toxic chemical listings):**  
None of the ingredients is listed.

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· **TSCA (Toxic Substances Control Act):**

25322-68-3	Polyethylene Glycol	ACTIVE
57-13-6	Urea	ACTIVE

· **Hazardous Air Pollutants**

None of the ingredients is listed.

· **Proposition 65**

· **Chemicals known to cause cancer:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for females:**

None of the ingredients is listed.

· **Chemicals known to cause reproductive toxicity for males:**

None of the ingredients is listed.

· **Chemicals known to cause developmental toxicity:**

None of the ingredients is listed.

· **Carcinogenic categories**

· **EPA (Environmental Protection Agency)**

57-13-6	Urea	II
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· **ACGIH Carcinogenicity (American Conference of Governmental Industrial Hygienists)**

None of the ingredients is listed.

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

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.

· **Department issuing SDS:** Environmental, Health, and Safety

· **Contact:** Customer Service

· **Date of preparation / last revision** 01/22/2025 / -

· **Abbreviations and acronyms:**

IMDG: International Maritime Code for Dangerous Goods

DOT: US Department of Transportation

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)

NFPA: National Fire Protection Association (USA)

HMIS: Hazardous Materials Identification System (USA)

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

OSHA: Occupational Safety & Health

TLV: Threshold Limit Value

PEL: Permissible Exposure Limit

REL: Recommended Exposure Limit

Acute Toxicity - Inhalation 4: Acute toxicity – Category 4

Skin Irritation 2: Skin corrosion/irritation – Category 2

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*Eye Irritation 2A: Serious eye damage/eye irritation – Category 2A*

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

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