

Safety Data SheetTrade Name: **FILE-RITE**

1.0 Commercial Product Name and Supplier											
1.1	Commercial product name / designation FILE-RITE™ Canal Lubricant and Chelating Agent										
1.2	Application / Use Dental material										
1.2.2	SIC 851 Human health activity										
1.2.3	Use Category 55										
1.3	Manufacturer Pulpdent Corporation 80 Oakland Street, P.O. Box 780 Watertown, MA 02472 USA Telephone: 1 617 926-6666 / Fax: 1 617 926-6262 Email: Pulpdent@pulpdent.com										
1.4	Emergency Telephone Number 1-800-535-5053 (24 Hour / USA)										
1.5	Authorized European Representative Advena Limited Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta										
	UK Responsible Person Advena Limited Pure Offices, Plato Close Warwick, CV34 6WE United Kingdom										
	CH Authorized Representative MedEnvoy Switzerland Gotthardstrasse 28, 6302 Zug, Switzerland										
2.0 Hazards Identification											
2.1	Classification Irritant (mild)										
2.1.1	Classification according to Regulation (EC) No. 1272/2008 [CLP] <table border="1"> <thead> <tr> <th>Hazard Class</th> <th>Hazard Category</th> <th>Hazard Statement</th> </tr> </thead> <tbody> <tr> <td>Eye irritation</td> <td>2</td> <td>H319</td> </tr> </tbody> </table>	Hazard Class	Hazard Category	Hazard Statement	Eye irritation	2	H319				
Hazard Class	Hazard Category	Hazard Statement									
Eye irritation	2	H319									
2.1.2	Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases) Xi (Irritant); R36										
2.2	GHS Label Elements Hazard Pictograms  Signal Word: Warning Restricted to use by dental professional only Hazard Statements: H319: Causes eye irritation. Category 2. Precautionary Statements: P305+P351+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.										
3.0 Composition											
3.1	Chemical characterization of the preparation of the product: Buffered ethylenediaminetetraacetic acid suspended in a gel matrix.										
3.2	Hazardous Ingredients <table border="1"> <thead> <tr> <th>CAS Number</th> <th>Name of the Ingredient</th> <th>Concentration</th> <th>Classification per 67/548/EEC</th> <th>Classification per Regulation (EC) No.1272/2008 (CLP).</th> </tr> </thead> <tbody> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </tbody> </table>	CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1272/2008 (CLP).					
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60-00-4	Ethylenediaminetetraacetic acid	17.0%	Xi (Irritant), R36	Eye irritation; Category 2
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4.0 First Aid Measures		
4.1	General Information	File-Rite, EDTA that has been buffered and suspended in a gel matrix, is non-hazardous. May cause mild, mechanical eye irritation. Show this SDS to medical personnel. Get medical attention in case of uncertainty.
4.2	Inhalation	Move person to fresh air. Seek medical attention if effects occur.
4.3	Skin Contact	Wash skin thoroughly with soap and water.
4.4	Eye Contact	Keep eyelids apart; flush with running water for 15+ minutes. Remove contact lenses after several minutes. If effects occur, consult an ophthalmologist.
4.5	Ingestion	For ingestion of large amounts (greater than in this product) contact Poison Control Center or physician. Induce vomiting only on medical advice. Never give anything by mouth to an unconscious person
4.6	Precautions for first responders	Wear safety glasses and gloves.
4.7	Information for physicians	
	Symptoms	Mild irritation/redness in eyes after contact.
	Hazards	May cause mild, mechanical eye irritation.
	Treatment	Same as above under First Aid.
5.0 Fire Fighting Measures		
5.1	Suitable extinguishing media	Whatever is appropriate for surrounding fire.
5.2	Extinguishing media to avoid	Decision should be based on surrounding fire.
5.3	Special exposure hazards in a fire	None
5.4	Special protective equipment for fire-fighters	Usual protective equipment is sufficient.
6.0 Accidental Release Measures		
6.1	Personal precautions.	Wear safety glasses, gloves and lab coat.
6.2	Environmental precautions	Follow all government regulations.
6.3	Method for clean up	Absorb/wipe up spill with paper towels or disposable cloths. Collect for disposal in covered container. Wash area of spill with soap and water.
7.0 Handling and Storage		
7.1	Handling	Medical device for intraoral use only dental professionals. Follow good hygiene practices. Recap syringe immediately after use.
7.2	Storage	Store product tightly capped in original container at cool room temperature (<25°C). Shelf life for unopened product is two years from date of manufacture, provided that material has been stored properly.
7.3	Specific uses	Dental material: Root canal lubricant and chelating agent.
8.0 Exposure Controls / Personal Protection		
8.1	Exposure limit values	PEL: Not established. TLV: Not established.
8.2	Exposure controls	
8.2.1	Occupational exposure controls	No special equipment
8.2.1.1	Respiratory protection	None required for File-Rite.

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8.2.1.2	Hand protection	No special requirements under normal conditions of use.
8.2.1.3	Eye protection	No special requirements under normal conditions of use
8.2.1.4	Skin protection	Good personal hygiene, lab coat, gloves.
8.2.1.5	Other controls	Emergency eye wash fountain should be available. Wash hands after use.
8.2.2	Environmental exposure controls	Follow all government regulations.

9.0 Physical and Chemical Properties

9.1	Characteristics	
9.1.1	Appearance /Color / Physical state	Pale orange transparent gel
9.1.2	Odor	None
9.2	Important health, safety and environmental information	
9.2.1	pH	6.8 to 7.4
9.2.2	Boiling point	212°F / 100°C
9.2.3	Flash point	Not applicable
9.2.4	Flammability (solid, gas)	Not applicable
9.2.5	Explosive properties	Not applicable
9.2.6	Oxidizing properties	Not applicable
9.2.7	Vapor pressure	Not determined
9.2.8	Specific gravity	1.102
9.2.9	Solubility in water	Soluble
9.2.10	Partition coefficient	Not determined
9.2.11	Viscosity	Not determined
9.2.12	Vapor density	Not determined
9.2.13	Evaporation rate	Not determined

10.0 Stability and reactivity

10.1	Conditions to avoid	None
10.2	Materials to avoid	Strong oxidizing agents
10.3	Hazardous decomposition products	Carbon monoxide, carbon dioxide, nitrogen oxides.
10.4	Further information	Stable material

11.0 Toxicological information

11.1	Acute toxicity	Not toxic. Oral rat LD50: 2000 mg/kg
11.2	Irritation and corrosiveness	May be irritating to eyes or skin on contact.
11.3	Sensitization	Not applicable
11.4	Sub-acute, sub-chronic, prolonged toxicity	None known
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known
11.6	Empirical data	Not available

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11.7	Clinical experience	File-Rite has been used safely and effectively by dental professionals in the US and internationally for more than 15 years with no reports of adverse effects.
12.0	Ecological Information	
12.1	Ecotoxicity	Not toxic. Follow all government regulations.
13.0	Disposal Considerations	
13.1	Regulations	Follow all local and national government regulations in disposing material or contaminated packaging.
14.0	Transport Information	
14.1	Restrictions	Non-hazardous material / Not regulated.
15.0	Regulatory Information	
15.1	EU	Class IIa medical device under MDD 93/42/EEC.
15.2	US FDA	Class II medical device
15.3	Health Canada	Class II medical device
16.0	Other information	
16.1	List of relevant R phrases	R36, Irritating to eyes.
16.2	Hazard Statements	H319: Causes eye irritation. Category 2.
16.3	Precautionary Statements	P305+P351+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
16.3	Restrictions on use	Pulpdent products are only sold to and used by dental professionals.
16.4	Further information	The information presented herein is believed to be factual as it has been derived from the works of persons believed to be qualified experts. However, nothing contained in this information is to be taken as a warranty or representation for which Pulpdent Corporation bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate.
16.5	Sources of key data	National Institute for Occupational Safety (NIOSH) US Occupational Safety and Health Administration (OSHA) Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH). Guidance on the compilation of safety data sheets. Version 1.1; December 2011. European Chemicals Agency
16.6	Information which has been added, deleted or revised.	This Safety Data Sheet has been revised to meet the requirements of GHS SDS format and Regulations (EC) No. 1272/2008 (CLP) and (EC) No. 1907/2006 (REACH). Specifically Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified.