


Safety Data Sheet

Trade 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, Importer		
1.3.1	Manufacturer		
	Pulpdent Corporation		
	80 Oakland Street	Telephone: 1 617 926-6666	
	P.O. Box 780	Fax: 1 617 926-6262	
	Watertown, MA 02472 USA	Email: Pulpdent@pulpdent.com	
1.4	Emergency Telephone Number	1-800-535-5053 (24 Hour / USA)	
1.5	Authorized European Representative		
	International Business Solutions Ltd.	Tel: 07989 407479 / Fax: 01256 350330	
	54 Mayfield Ridge	Email: s.williams5@btconnect.co.uk	
	Hatch Warren, Basingstoke, RG22 4RS UK		
2.0 Hazards Identification			
2.1	Classification	Irritant (mild)	
2.1.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	<u>Hazard Class</u>	<u>Hazard Category</u> <u>Hazard Statement</u>
		Eye irritation	2 H320
2.1.2	Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases)	Xi (Irritant); R36	
2.2 Label Elements			
	Labeling according to Regulation (EC) No 1272/2008 [CLP]		
	Hazard Pictograms		
			
	Signal Word: Warning		
	Restricted to use by dental professional only		
	Hazard Statements:		
	H320: 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.		

Safety Data Sheet

Trade Name: **FILE-RITE**

3.0 Composition

- 3.1 Chemical characterization of the preparation: File-Rite is buffered ethylenediaminetetraacetic acid suspended in a gel matrix.

3.2 Hazardous Ingredients

CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1278/2008 (CLP).
60-00-4	Ethylenediaminetetraacetic acid	17.0%	Xi (Irritant), R36	Eye irritation; Category 2

4.0 First Aid Measures

- 4.1 General Information
File-Rite, ETDA that has been buffered and suspended in a gel matrix, is non-hazardous. File-Rite Gel may cause mild, mechanical eye irritation. Show this safety data sheet 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 and 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 or wipe up spill with suitable material (paper towels or disposable cloths). Collect for disposal in a covered container. Wash area of spill with soap and water.

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

7.0	Handling and Storage	
7.1	Handling	Medical device for intraoral use only by trained dental professionals. Follow good hygiene practices. Do not smoke, eat or drink while using. Recap syringe immediately after use.
7.2	Storage	Keep container closed. Store product in original container at cool room temperature (<25°C). Shelf life for unopened product is two years from date of manufacture, provided that the 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.
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	No special requirements other than good personal hygiene, lab coat and 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	Appearance / Color	
9.1.1	Color	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

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

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 and prolonged toxicity	None known
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known
11.6	Empirical data	Not available
11.7	Clinical experience	File-Rite has been on the market 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.
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13.0 Disposal Considerations

13.1	Regulations	Follow all local and national government regulations in disposing material or contaminated packaging.
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14.0 Transport Information

14.1	Restrictions	Non-hazardous material / Not regulated.
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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	H320: Causes eye irritation. Category 2.

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

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 to be sold to and used by dental professionals only.
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.
