

Safety Data Sheet

According to Regulation (EC) No. 1907/2006 (REACH)

Trade Name: **FILE-RITE**

1.0 Commercial Product Name and Supplier		
1.1	Commercial product name / designation	<i>FILE-RITE™ Canal Lubricant and Chelating Agent</i>
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	<p>Pulpdent Corporation 80 Oakland Street P.O. Box 780 Watertown, MA 02472 USA</p> <p>Telephone: 1 617 926-6666 Fax: 1 617 926-6262 Email: Pulpdent@pulpdent.com</p>
1.4	Emergency Telephone Number	1-800-535-5053 (24 Hour / USA)
1.5	Authorized European Representative	<p>International Business Solutions Ltd. 54 Mayfield Ridge Hatch Warren, Basingstoke, RG22 4RS UK Tel: 07989 407479 / Fax: 01256 350330 Email: scwcqc@globalnet.co.uk</p>
2.0 Hazards Identification		
2.1	Classification	Irritant (mild)
2.2	Adverse human health effects	<p>File-Rite gel is non-hazardous.</p> <p>EDTA powder may cause mild, mechanical eye irritation, mild skin irritation and sneezing or coughing on inhalation.</p>
3.0 Composition		
3.1	Chemical composition of the preparation	Chemical composition of the preparation: File-Rite is EDTA suspended in a gel matrix.

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Trade Name: **FILE-RITE****3.2 Hazardous Ingredients**

CAS Number	EC Number	Name of the Ingredient	Concentration	Warning symbol, R phrases
139-33-3	205-358-3	Ethylenediaminetetraacetic acid, disodium salt	17.0%	Xi (powder only), R36

4.0 First Aid Measures

4.1	General Information	File-Rite, Na EDTA suspended in a gel matrix, is non-hazardous. EDTA <i>powder</i> may cause mild, mechanical eye irritation, mild skin irritation and sneezing or coughing on inhalation. 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. If a large amount of EDTA powder is present, wear a dust mask.
4.7	Information for physicians	
	Symptoms	Mild irritation/redness in eyes or on skin after contact. Sneezing or coughing after inhalation of powder.
	Hazards	EDTA <i>powder</i> may cause mild, mechanical eye irritation, mild skin irritation and sneezing or coughing on inhalation.
	Treatment	Same as above under First Aid.

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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.
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	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 other than the usual surgical gloves worn by dental staff.
8.2.1.3	Eye protection	No special requirements other than the usual safety

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		glasses worn by dental staff.
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

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

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10.2	Materials to avoid	Strong oxidizing agents
10.3	Hazardous decomposition products	Burning may produce 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: 2000mg/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	Using Na EDTA as part of root canal treatment is a well-established (more than 20 years), industry-accepted, endodontic practice. Na EDTA is considered to be safe and effective treatment in the hands of a dental professional.

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 Regulations	File-Rite is a Class IIA Medical Device under the Medical Devices Directive 93/42/EEC.
15.1	Information on the warning label	

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15.1.1	Hazard symbol	None for FILE-RITE
15.1.2	Hazardous ingredient	Ethylenediaminetetraacetic acid, disodium salt
15.1.3	Risk phrases	R36: Irritant to eyes.
15.1.4	Safety phrases	S25: Avoid contact with eyes
16.0	Other information	
16.1	List of relevant R phrases	R36, Irritant to eyes.
16.2	Training advice	Pulpdent products are for use by dental professionals only.
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) Occupational Safety and Health Administration (OSHA) Eur-Lex European Union Law
16.6	Information which has been added, deleted or revised.	This Safety Data Sheet has been revised to meet the requirements of Regulation (EC) No. 1907/2006 (REACH).