


Safety Data SheetTrade Name: **EDTA Solution, 17%, File-Rite, Prep-Rite RC**

1.0 Commercial Product Name and Supplier	
1.1	Commercial product name / designation
	EDTA PREPARATIONS <i>EDTA Solution, 17%</i> <i>File-Rite</i> <i>Prep-Rite RC</i>
1.2	Application / Use
1.2.2	SIC
1.2.3	Use Category
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
1.5	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
2.1.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]
	EDTA, 17% Solution
	<i>Unincorporated powder only</i>
	File-Rite
	<i>(powder only)</i>
	Prep-Rite RC
	<i>(powder only)</i>
2.2	GHS Label Elements
	Hazard Pictograms
	
	Signal Word: Warning
	Restricted to use by dental professional only
	Hazard Statements:
	<i>Unincorporated powder only</i>
	H319: Causes serious eye irritation. Category 2.

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H315: Causes skin 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.

P302+P352: If on skin, wash with plenty of soap and water.

3.0 Composition				
3.1	Chemical characterization of the preparation			
3.2	Hazardous Ingredients			
	CAS Number	Name of the Ingredient	Concentration	Classification per Regulation (EC) No.1272/2008 (CLP).
	60-00-4	Ethylenediaminetetraacetic acid	EDTA: 17%	<i>Unincorporated powder only</i> Eye irritation; Category 2 Skin irritation; Category 2
			File-Rite: 17%	Eye irritation; Category 2 Skin irritation; Category 2
			Prep-Rite RC: 15%	Eye irritation; Category 2 Skin irritation; Category 2
4.0 First Aid Measures				
4.1	General Information		Finished paste products present a minimal danger to health under normal conditions of use and in the quantities necessary for dental procedures. It can be irritating to the eyes or skin from contact or prolonged exposure.	
4.2	Inhalation		Move person to fresh air. If effects occur, seek medical attention.	
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. Consult an ophthalmologist for persistent irritation	
4.5	Ingestion		Large amounts: contact Poison Control Center or physician. Induce vomiting only on medical advice.	
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.	
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.	

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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	Liquid: Absorb or wipe up spill with paper towels or disposable cloths. Collect for disposal in covered container. Wash area with soap and water. Collect powder spill without dispersing into air. Place material in covered container. Wash area of spill with soap and water.
7.0	Handling and Storage	
7.1	Handling	<i>For intraoral use only</i> by trained dental professionals. Follow good hygiene practices. Do not smoke, eat or drink while using.
7.2	Storage	Keep container closed. Store product in original container at cool room temperature (< 25°C). Shelf life for unopened product is three years from date of manufacture, provided proper storage.
7.3	Specific uses	Dental chelating agent used to debride root canals.
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 required.
8.2.1.1	Respiratory protection	None required under normal conditions of use.
8.2.1.2	Hand protection	No special requirements under normal conditions of use.
8.2.1.3	Eye protection	Safety glasses
8.2.1.4	Skin protection	Good personal hygiene, lab coat and gloves. Wash hands after use.
8.2.1.5	Other controls	Emergency eye wash fountain close by.
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	EDTA 17% Solution: Clear, colorless liquid File-Rite: Pale orange, transparent gel Prep-Rite RC: White, translucent gel
9.1.2	Odor	None
9.2	Important health, safety and environmental information	
9.2.1	pH	6.8 to 7.4 (EDTA) 6.5 to 8 (File-Rite) 3.8 to 8 (Prep-Rite RC)
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

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9.2.8	Specific gravity	EDTA, 17% Solution: 1.000 File-Rite: 1.102 Prep-Rite RC: 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 known
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	EDTA preparations have been used for decades with a high benefit-risk ratio. No significant risks are known in the short or long term of any actual problems after thousands of procedures.
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.
14.0	Transport Information	
14.1	Restrictions	Non-hazardous material / Not regulated.
15.0	Regulatory Information	
15.1	EU	Class IIa medical device under the 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	Hazard Statements	H319: Causes serious eye irritation. Category 2. H315: Causes skin irritation. Category 2.
16.2	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. P302+P352: If on skin, wash with plenty of soap and water.

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16.3	Restrictions on use	Pulpdent products are for use 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), Regulation (EU) No 487/2013 and Regulation (EC) No. 1907/2006 (REACH). European Chemicals Agency Guidance on the compilation of safety data sheets Version 4.0 April 2020
16.6	Information which has been added, deleted or revised.	This Safety Data Sheet has been revised to meet the requirements of the GHS SDS format, Regulations (EC) No. 487/2013 (CLP), , (EC) No. 1907/2006 (REACH) and ECHA Version 4.0 April 2020.
