

Safety Data Sheet

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

Trade Name: **EDTA Solution, 17%**

1.0 Commercial Product Name and Supplier											
1.1	Commercial product name / designation <i>EDTA Solution, 17%</i>										
1.2	Application / Use Dental chelating agent used to debride root canals.										
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 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 International Business Solutions Ltd. 54 Mayfield Ridge Hatch Warren, Basingstoke, RG22 4RS UK Tel: 07989 407479 / Fax: 01256 350330 Email: scwcqc@globalnet.co.uk										
2.0 Hazards Identification											
2.1	Classification Irritant (mild)										
2.2	Adverse human health effects EDTA, 17% solution is non-hazardous. EDTA <i>powder</i> may cause mild, mechanical eye irritation, mild skin irritation and sneezing or coughing on inhalation.										
3.0 Composition											
3.1	Chemical characterization of the preparation 17% aqueous solution of Na EDTA powder.										
3.2	Hazardous Ingredients										
	<table border="1"> <thead> <tr> <th>CAS Number</th> <th>EC Number</th> <th>Name of the Ingredient</th> <th>Concentration</th> <th>Warning symbol / R phrases</th> </tr> </thead> <tbody> <tr> <td>139-33-3</td> <td>205-358-3</td> <td>Ethylenediaminetetraacetic acid, disodium salt</td> <td>17.0%</td> <td>Xi (powder only) / R36</td> </tr> </tbody> </table>	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
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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 EDTA, 17% solution is non-hazardous. EDTA <i>powder</i> may cause mild, mechanical eye irritation, mild skin irritation, sneezing or coughing on inhalation. Show this safety data sheet to medical										

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		personnel. Get medical attention in case of uncertainty.
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.
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 liquid spill with suitable material (paper towels or disposable cloths). Collect for disposal in a covered container. Wash area of spill with soap and water. Collect powder spill without dispersing into air. Place material in covered container. Wash are of spill with soap and water.
7.0	Handling and Storage	
7.1	Handling	For intraoral use only 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 two years from date of manufacture, provided proper storage.

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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 of EDTA, 17% solution.
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 and maintained.
8.2.2	Environmental exposure controls	Follow all government regulations.
9.0	Physical and Chemical Properties	
9.1	Appearance / Color	
9.1.1	Color	Clear, colorless liquid
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	1.000
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.

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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 NaEDTA as part of root canal treatment is a well-established (20+ years), industry-accepted, endodontic practice. NaEDTA 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.
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 Regulations	Class IIA Medical Device under the MDD 93/42/EEC.
15.2	Information on the warning label	
15.2.1	Hazard symbol	None for EDTA Solution, 17%
15.2.2	Hazardous ingredient	Ethylenediaminetetraacetic acid, disodium salt
15.2.3	Risk phrases	R36, Irritating to eyes.
15.2.4	Safety phrases	S25, Avoid contact with eyes.
16.0	Other information	
16.1	List of relevant R phrases	R36, Irritating to eyes.
16.2	Training advice	Pulpdent products are for use by dental professionals only.
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)

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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).
