SAFETY DATA SHEETS

This SDS packet was issued with item:

075896485

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

070544536 075896493 075896501 271177013

Safety Data Sheet

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

1.0	**Commercial Product Name and Supplier**	
1.1	Commercial product name / designation	*EDTA Solution, 17%*
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: s.williams5@btconnect.co.uk

2.0	**Hazards Identification**			
2.1	Classification			
2.1.1	**Classification according to Regulation (EC) No. 1272/2008 [CLP]**	Hazard Class	Hazard Category	Hazard Statement
	Unincorporated powder only	Eye irritation	2	H319
	Unincorporated powder only	Skin irritation	2	H315
2.1.2	**Classification according to Directive 67/548/EEC** *(See SECTION 16 for full text of risk phrases)*	Irritant (Xi) *(powder only)*; R36/38		

2.2 Label Elements

Labeling according to Regulation (EC) No 1272/2008 [CLP]

Hazard Pictograms

Signal Word: **Warning**

Safety Data Sheet

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

Restricted to use by dental professional only

Hazard Statements:

Unincorporated powder only

H319: Causes serious eye irritation. Category 2.

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 — 17% aqueous solution of ethylenediaminetetraacetic acid

3.2 Hazardous Ingredients

CAS Number	Name of the Ingredient	Concentration	Classification according to 67/548/EEC	Classification according to Regulation (EC) No.1278/2008 (CLP).
60-00-4	Ethylenediaminetetraacetic acid	17%	*Unincorporated powder only* Irritant (Xi) / R36/38	*Unincorporated powder only* Eye irritation; Category 2 Skin irritation; Category 2

4.0 First Aid Measures

4.1	General Information	EDTA, 17% solution is non-hazardous. EDTA *powder* may cause mild, mechanical eye irritation or mild skin irritation. Powder may present as a nuisance dust. Show this safety data sheet to medical 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 *powder* may cause mild, mechanical eye irritation, mild skin irritation and sneezing or coughing on inhalation.
	Treatment	Same as above under First Aid.

Safety Data Sheet

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

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 area 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^{O}C). Shelf life for unopened product is two 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 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.
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	EDTA, 17% Solution has been on the market in the US and internationally for more than 15 years. Using EDTA 17% Solution as part of root canal treatment is a well-established (20+ years), industry-accepted, endodontic practice. 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.

Safety Data Sheet

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

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	List of relevant R phrases	R36, Irritating to eyes. R38, Irritating to skin.
16.2	Hazard Statements	H319: Causes serious eye irritation. Category 2. H315: Causes skin 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. P302+P352: If on skin, wash with plenty of soap and water.
16.4	Restrictions on use	Pulpdent products are for use by dental professionals only.
16.5	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.
16.6	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
16.7	Information which has been added, deleted or revised.	This Safety Data Sheet has been revised to meet the requirements of the 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.

Safety Data Sheet

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

1.0 Commercial Product Name and Supplier

1.1	Commercial product name / designation	*EDTA Solution, 17%*
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	
	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 Ltd. Pure Offices, Plato Close Warwick, CV34 6WE United Kingdom

2.0 Hazards Identification

2.1 Classification

2.1.1 Classification according to Regulation (EC) No. 1272/2008 [CLP]
Unincorporated powder only

Hazard Class	Hazard Category	Hazard Statement
Eye irritation	2	H319
Skin irritation	2	H315

2.1.2 Classification per Directive 67/548/EEC: Irritant (Xi) *(powder only)*;R36/38 *(Section 16 for full text of risk phrases)*

2.2 GHS Label Elements

Hazard Pictograms

Signal Word: Warning

Restricted to use by dental professional only

Hazard Statements:

Unincorporated powder only

H319: Causes serious eye irritation. Category 2.

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: 17% aqueous solution of ethylenediaminetetraacetic acid

3.2 Hazardous Ingredients

CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1272/2008 (CLP).
60-00-4	Ethylenediaminetetraacetic acid	17%	*Unincorporated powder only* Irritant (Xi) / R36/38	*Unincorporated powder only* Eye irritation; Category 2 Skin irritation; Category 2

Safety Data Sheet

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

4.0	First Aid Measures	
4.1	General Information	EDTA, 17% solution is non-hazardous. EDTA *powder* may cause mild, mechanical eye irritation or mild skin irritation. Powder may present as a nuisance dust. Show this safety data sheet to medical 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 *powder* 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	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	*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^{o}C). Shelf life for unopened product is two years from date of manufacture, provided proper storage.
7.3	Specific uses	Dental chelating agent used to debride root canals.

Safety Data Sheet

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

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.
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	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.
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

Safety Data Sheet

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

11.6	Empirical data	Not available
11.7	Clinical experience	Using EDTA as part of root canal treatment is a well-established (20+ years), industry-accepted, safe/effective endodontic practice.
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	List of relevant R phrases	R36, Irritating to eyes. R38, Irritating to skin.
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