

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 SheetTrade 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 <i>Pulpdent Corporation</i> 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 |
| | <i>Unincorporated powder only</i> | Eye irritation | 2 | H319 |
| | <i>Unincorporated powder only</i> | 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 SheetTrade 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 SheetTrade Name: **EDTA Solution, 17%**

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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 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 | <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 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 | |


Safety Data SheetTrade Name: **EDTA Solution, 17%**

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|-------------|--|---|
| 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 SheetTrade Name: **EDTA Solution, 17%**

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| 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 SheetTrade 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 | | Telephone: 1 617 926-6666 / Fax: 1 617 926-6262 Email: Pulpdent@pulpdent.com | |
| | Pulpdent Corporation | | | |
| | 80 Oakland Street, P.O. Box 780 Watertown, MA 02472 USA | | | |
| 1.4 | Emergency Telephone Number | | 1-800-535-5053 (24 Hour / USA) | |
| 1.5 | Authorized European Representative | | Advena Limited Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta | |
| 2.0 Hazards Identification | | | | |
| 2.1 | Classification | | | |
| 2.1.1 | Classification according to Regulation (EC) No. 1272/2008 [CLP] | | <u>Hazard Class</u> | <u>Hazard Category</u> |
| | <i>Unincorporated powder only</i> | | Eye irritation | 2 |
| | | | Skin irritation | 2 |
| 2.1.2 | Classification per Directive 67/548/EEC | | Irritant (Xi) (<i>powder only</i>);R36/38 (<i>Section 16 for full text of risk phrases</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. | | | |
| | 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 | Concent ration | Classification per 67/548/EEC |
| | 60-00-4 | Ethylenediaminetetraacetic acid | 17% | <i>Unincorporated powder only</i> |
| | | | | <i>Unincorporated powder only</i> |

Safety Data SheetTrade Name: **EDTA Solution, 17%**

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|-----|--|---|------------------------|---|
| | | | Irritant (Xi) / R36/38 | Eye irritation; Category 2 Skin irritation; Category 2 |
| 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 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 <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 | 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 two years from date of manufacture, provided proper storage. | | |

Safety Data SheetTrade Name: **EDTA Solution, 17%**

| | | |
|-------------|--|---|
| 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. |
| 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 |

Safety Data SheetTrade Name: **EDTA Solution, 17%**

| | | |
|------|--|--|
| 11.5 | Carcinogenicity, Mutagenicity, Reproductive Toxicity | None known |
| 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. |
| 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%***