


**Safety Data Sheet**Trade Name: **Prep-Rite RC**

| 1.0 Commercial Product Name and Supplier |  |   |                     |                        |                         |                                   |   |      |                                    |   |      |  |
|--|--|---|---------------------|------------------------|-------------------------|-----------------------------------|---|------|------------------------------------|---|------|--|
| 1.1                                      | Commercial product name / designation  | <b>Prep-Rite RC 15% EDTA Gel</b>  |                     |                        |                         |                                   |   |      |                                    |   |      |  |
| 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   | <b>Pulpdent Corporation</b><br>80 Oakland Street, P.O. Box 780<br>Watertown, MA 02472 USA<br>Telephone: 1 617 926-6666 / Fax: 1 617 926-6262<br>Email: <a href="mailto:Pulpdent@pulpdent.com">Pulpdent@pulpdent.com</a>   |                     |                        |                         |                                   |   |      |                                    |   |      |  |
| 1.4                                      | Emergency Telephone Number   | 1-800-535-5053 (24 Hour / USA)  |                     |                        |                         |                                   |   |      |                                    |   |      |  |
| 1.5                                      | Authorized European Representative   | Advena Limited<br>Tower Business Centre, 2nd Floor,<br>Tower Street,<br>Swatar, BKR 4013 Malta  |                     |                        |                         |                                   |   |      |                                    |   |      |  |
|  | UK Responsible Person  | Advena Limited<br>Pure Offices, Plato Close<br>Warwick, CV34 6WE United Kingdom   |                     |                        |                         |                                   |   |      |                                    |   |      |  |
|  | CH Authorized Representative   | MedEnvoy Switzerland<br>Gotthardstrasse 28, 6302 Zug, Switzerland   |                     |                        |                         |                                   |   |      |                                    |   |      |  |
| 2.0 Hazards Identification               |  |   |                     |                        |                         |                                   |   |      |                                    |   |      |  |
| 2.1                                      | Classification   |   |                     |                        |                         |                                   |   |      |                                    |   |      |  |
| 2.1.1                                    | Classification according to Regulation (EC) No. 1272/2008 [CLP]  | <table border="1"> <thead> <tr> <th><u>Hazard Class</u></th> <th><u>Hazard Category</u></th> <th><u>Hazard Statement</u></th> </tr> </thead> <tbody> <tr> <td><i>Powder only</i> Eye irritation</td> <td>2</td> <td>H319</td> </tr> <tr> <td><i>Powder only</i> Skin irritation</td> <td>2</td> <td>H315</td> </tr> </tbody> </table> | <u>Hazard Class</u> | <u>Hazard Category</u> | <u>Hazard Statement</u> | <i>Powder only</i> Eye irritation | 2 | H319 | <i>Powder only</i> Skin irritation | 2 | H315 |  |
| <u>Hazard Class</u>                      | <u>Hazard Category</u>   | <u>Hazard Statement</u>   |                     |                        |                         |                                   |   |      |                                    |   |      |  |
| <i>Powder only</i> Eye irritation        | 2  | H319  |                     |                        |                         |                                   |   |      |                                    |   |      |  |
| <i>Powder only</i> Skin irritation       | 2  | H315  |                     |                        |                         |                                   |   |      |                                    |   |      |  |
| 2.1.2                                    | Classification according to Directive 67/548/EEC   | Irritant (Xi); R36/38 (See SECTION 16 for full text of risk phrases)  |                     |                        |                         |                                   |   |      |                                    |   |      |  |
| 2.2                                      | <b>GHS Label Elements</b>  |   |                     |                        |                         |                                   |   |      |                                    |   |      |  |
|  | Hazard Pictograms  |   |                     |                        |                         |                                   |   |      |                                    |   |      |  |
|  |   |   |                     |                        |                         |                                   |   |      |                                    |   |      |  |
|  | Signal Word: <b>Warning</b>  |   |                     |                        |                         |                                   |   |      |                                    |   |      |  |
|  | <b>Restricted to use by dental professional only</b>   |   |                     |                        |                         |                                   |   |      |                                    |   |      |  |
|  | <b>Hazard Statements:</b>  |   |                     |                        |                         |                                   |   |      |                                    |   |      |  |
|  | <i>Powder only</i>   |   |                     |                        |                         |                                   |   |      |                                    |   |      |  |
|  | H319: Causes serious eye irritation. Category 2.   |   |                     |                        |                         |                                   |   |      |                                    |   |      |  |
|  | H315: Causes skin irritation. Category 2.  |   |                     |                        |                         |                                   |   |      |                                    |   |      |  |
|  | <b>Precautionary Statements:</b>   |   |                     |                        |                         |                                   |   |      |                                    |   |      |  |
|  | 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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| <b>3.0 Composition</b>                 |  |   |               |   |
|--|--|---|---------------|---|
| 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   |
|  | 60-00-4  | Ethylenediaminetetraacetic acid   | 15%           | <i>Powder only</i><br>Irritant (Xi) / R36/38  |
|  |  |   |               | Classification per Regulation (EC) No.1272/2008 (CLP).<br><i>Powder only</i><br>Eye irritation; Category 2<br>Skin irritation; Category 2 |
| <b>4.0 First Aid Measures</b>          |  |   |               |   |
| 4.1                                    | General Information                            | <i>Prep-Rite RC</i> , buffered EDTA suspended in a viscous gel matrix, is non-hazardous. <i>EDTA 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  | <i>EDTA powder</i> may cause mild, mechanical eye irritation, mild skin irritation and sneezing or coughing on inhalation.  |               |   |
|  | Treatment                                      | Same as above under First Aid.  |               |   |
| <b>5.0 Fire Fighting Measures</b>      |  |   |               |   |
| 5.1                                    | Suitable extinguishing media                   | Decision should be based on 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.   |               |   |
| <b>6.0 Accidental Release Measures</b> |  |   |               |   |
| 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 <i>liquid</i> spill with paper towels or disposable cloths. Collect for disposal in a covered container. Collect <i>powder</i> spill without dispersing into air. Wash area of spill with soap and water.   |               |   |
| <b>7.0 Handling and Storage</b>        |  |   |               |   |
| 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.   |               |   |

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7.2 Storage Store tightly capped 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 Root canal lubricant and dental 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 required.

8.2.1.1 Respiratory protection None required

8.2.1.2 Hand protection Surgical gloves.

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 White, translucent gel

9.1.2 Odor None

9.2 Important health, safety and environmental information

9.2.1 pH 3.8 to 8

9.2.2 Boiling point Not determined

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 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

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|             |  |  |
|-------------|--|--|
| <b>11.0</b> | <b>Toxicological information</b>                     |  |
| 11.1        | Acute toxicity                                       | Not toxic. Oral rat LD <sub>50</sub> : 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                                  | Using EDTA preparations as part of root canal treatment is a well-established (20+ years), industry-accepted, endodontic practice..  |
| <b>12.0</b> | <b>Ecological Information</b>                        |  |
| 12.1        | Ecotoxicity  | Not toxic. Follow all government regulations.  |
| <b>13.0</b> | <b>Disposal Considerations</b>                       |  |
| 13.1        | Regulations  | Follow all local and national government regulations.  |
| <b>14.0</b> | <b>Transport Information</b>                         |  |
| 14.1        | Restrictions   | Non-hazardous material / Not regulated.  |
| <b>15.0</b> | <b>Regulatory Information</b>                        |  |
| 15.1        | EU   | Class IIa medical device under MDD 93/42/EEC.  |
| 15.2        | US FDA   | Class II medical device  |
| 15.3        | Health Canada  | Class II medical device  |
| <b>16.0</b> | <b>Other information</b>                             |  |
| 16.1        | List of relevant R phrases                           | R36, Irritating to eyes.<br>R38, Irritating to skin.   |
| 16.2        | Hazard Statements                                    | H319: Causes serious eye irritation. Category 2.<br>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.<br>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)<br>US Occupational Safety and Health Administration (OSHA)<br>Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH).<br>Guidance on the compilation of safety data sheets. Version 1.1; December 2011. European Chemicals Agency  |

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16.7 Information which has been added, deleted or revised.

This Safety Data Sheet has been revised to meet the requirements of GHS SDS format and Regulations (EC) No. 1272/2008 (CLP) and 1907/2006 (REACH). Specifically Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified.

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