


**Safety Data Sheet**Trade Name: **FILE-RITE**

| 1.0 Commercial Product Name and Supplier |  |   |                                 |                         |                               |  |
|--|--|---|---------------------------------|-------------------------|-------------------------------|--|
| 1.1                                      | Commercial product name / designation  | <b>FILE-RITE™ Canal Lubricant and Chelating Agent</b>   |                                 |                         |                               |  |
| 1.2                                      | Application / Use  | Dental material   |                                 |                         |                               |  |
| 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<br>Malta   |                                 |                         |                               |  |
| 2.0 Hazards Identification               |  |   |                                 |                         |                               |  |
| 2.1                                      | Classification   | Irritant (mild)   |                                 |                         |                               |  |
| 2.1.1                                    | Classification according to Regulation (EC) No. 1272/2008 [CLP]  | <u>Hazard Class</u>   | <u>Hazard Category</u>          | <u>Hazard Statement</u> |                               |  |
|  |  | Eye irritation  | 2                               | H319                    |                               |  |
| 2.1.2                                    | Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases)  | Xi (Irritant); R36  |                                 |                         |                               |  |
| 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>  |   |                                 |                         |                               |  |
|  | H319: Causes eye 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. |   |                                 |                         |                               |  |
| 3.0 Composition                          |  |   |                                 |                         |                               |  |
| 3.1                                      | Chemical characterization of the preparation   | Clear, white, translucent, buffered ethylenediaminetetraacetic acid suspended in a gel matrix.  |                                 |                         |                               |  |
| 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 | 17.0%                   | Xi (Irritant), R36            | Eye irritation; Category 2                             |

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| <b>4.0 First Aid Measures</b>                      |  |  |
|--|--|--|
| 4.1  | General Information                            | File-Rite, EDTA that has been buffered and suspended in a gel matrix, is non-hazardous. May cause mild, mechanical eye irritation. Show this SDS to medical personnel. Get medical attention in case of uncertainty. |
| 4.2  | Inhalation                                     | Move person to fresh air. Seek medical attention if effects occur.   |
| 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. If effects occur, consult an ophthalmologist.   |
| 4.5  | Ingestion                                      | For ingestion of large amounts (greater than in this product) contact Poison Control Center or physician. Induce vomiting only on medical advice. Never give anything by mouth to an unconscious person              |
| 4.6  | Precautions for first responders               | Wear safety glasses and gloves.  |
| 4.7  | Information for physicians                     |  |
|  | Symptoms                                       | Mild irritation/redness in eyes after contact.   |
|  | Hazards  | May cause mild, mechanical eye irritation.   |
|  | Treatment                                      | Same as above under First Aid.   |
| <b>5.0 Fire Fighting Measures</b>                  |  |  |
| 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.  |
| <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/wipe up spill with paper towels or disposable cloths. Collect for disposal in covered container. Wash area of spill with soap and water.  |
| <b>7.0 Handling and Storage</b>                    |  |  |
| 7.1  | Handling                                       | Medical device for intraoral use only dental professionals. Follow good hygiene practices. Recap syringe immediately after use.  |
| 7.2  | Storage  | Store product tightly capped in original container at cool room temperature (<25°C). Shelf life for unopened product is two years from date of manufacture, provided that material has been stored properly.         |
| 7.3  | Specific uses                                  | Dental material: Root canal lubricant and chelating agent.   |
| <b>8.0 Exposure Controls / Personal Protection</b> |  |  |
| 8.1  | Exposure limit values                          | PEL: Not established. TLV: Not established.  |
| 8.2  | Exposure controls                              |  |
| 8.2.1  | Occupational exposure controls                 | No special equipment   |
| 8.2.1.1  | Respiratory protection                         | None required for File-Rite.   |

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|         |                                 |  |
|---------|---------------------------------|--|
| 8.2.1.2 | Hand protection                 | No special requirements under normal conditions of use.                |
| 8.2.1.3 | Eye protection                  | No special requirements under normal conditions of use                 |
| 8.2.1.4 | Skin protection                 | Good personal hygiene, lab coat, gloves.                               |
| 8.2.1.5 | Other controls                  | Emergency eye wash fountain should be available. Wash hands after use. |
| 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                     | Pale orange transparent gel |
| 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                                       | 1.102                       |
| 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  |
| 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, prolonged toxicity           | None known                                    |
| 11.5 | Carcinogenicity, Mutagenicity, Reproductive Toxicity | None known                                    |

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|      |                     |   |
|------|---------------------|---|
| 11.6 | Empirical data      | Not available   |
| 11.7 | Clinical experience | File-Rite has been used safely and effectively by dental professionals in the US and internationally for more than 15 years with no reports of adverse effects. |

**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 in disposing material or contaminated packaging. |
|------|-------------|---|

**14.0 Transport Information**

|      |              |   |
|------|--------------|---|
| 14.1 | Restrictions | Non-hazardous material / Not regulated. |
|------|--------------|---|

**15.0 Regulatory Information**

|      |               |   |
|------|---------------|---|
| 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                       |

**16.0 Other information**

|      |   |  |
|------|---|--|
| 16.1 | List of relevant R phrases                            | R36, Irritating to eyes.   |
| 16.2 | Hazard Statements                                     | H319: Causes eye 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.   |
| 16.3 | Restrictions on use                                   | Pulpdent products are only sold to and used by dental professionals.   |
| 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)<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  |
| 16.6 | 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 (EC) No. 1907/2006 (REACH). Specifically Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified.  |