

Safety Data Sheet

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

Trade Name: **DRY-RITE**

| 1.0 Commercial Product Name and Supplier | | | | | | | | | | | | | | | | |
|--|---|------------------------|---------------|---------------------------------|---------------|---------------------------|---------|-----------|---------------|-----|-------|---------|-----------|----------------------|----|---------------------------------|
| 1.1 | Commercial product name / designation <i>Dry-Rite</i> Drying Agent | | | | | | | | | | | | | | | |
| 1.2 | Application / Use Dental material for use by dental professionals. | | | | | | | | | | | | | | | |
| 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 Class 3, Flammable liquid | | | | | | | | | | | | | | | |
| 2.2 | Adverse human health effects May cause irritation of eyes or skin on contact. May cause irritation of respiratory tract if inhaled. Exposure to ethanol >1000 ppm may cause headache, drowsiness, lassitude, appetite loss. | | | | | | | | | | | | | | | |
| 3.0 Composition | | | | | | | | | | | | | | | | |
| 3.1 | Chemical characterization of the preparation: Denatured ethyl alcohol preparation. | | | | | | | | | | | | | | | |
| 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>64-17-5</td> <td>200-578-6</td> <td>Ethyl alcohol</td> <td>92%</td> <td>F R11</td> </tr> <tr> <td>67-64-1</td> <td>200-662-2</td> <td>Acetone (denaturant)</td> <td>7%</td> <td>F, Xi. R11 - 36/ 37/38 - 66-67.</td> </tr> </tbody> </table> | CAS Number | EC Number | Name of the Ingredient | Concentration | Warning symbol, R phrases | 64-17-5 | 200-578-6 | Ethyl alcohol | 92% | F R11 | 67-64-1 | 200-662-2 | Acetone (denaturant) | 7% | F, Xi. R11 - 36/ 37/38 - 66-67. |
| CAS Number | EC Number | Name of the Ingredient | Concentration | Warning symbol, R phrases | | | | | | | | | | | | |
| 64-17-5 | 200-578-6 | Ethyl alcohol | 92% | F R11 | | | | | | | | | | | | |
| 67-64-1 | 200-662-2 | Acetone (denaturant) | 7% | F, Xi. R11 - 36/ 37/38 - 66-67. | | | | | | | | | | | | |

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| 4.0 First Aid Measures | | |
|--|--|--|
| 4.1 | General Information | May cause irritation of eyes or skin on contact. May cause irritation of respiratory tract if inhaled. Exposure to ethanol >1000 ppm may cause headache, drowsiness, lassitude, appetite loss. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty. |
| 4.2 | Eye Contact | Keep eyelids apart, flush with running water for 15+ minutes. Get medical attention. |
| 4.3 | Skin Contact | Remove contaminated clothing. Immediately wash with soap, running water. Use hand cream. Get medical attention if irritation persists. |
| 4.4 | Ingestion | Rinse mouth with water. Do not induce vomiting. Get immediate medical attention. Never give anything by mouth to an unconscious person. |
| 4.5 | Inhalation | Move to fresh air. If necessary, administer oxygen and/or artificial respiration; seek medical attention. |
| 4.6 | Precautions for first responders | Ventilate the area. Wear safety glasses and gloves. |
| 4.7 | Information for physicians | |
| | Symptoms | Contact with material may cause irritation or redness in eyes or on skin. Inhalation may cause irritation of respiratory tract. |
| | Hazards | Exposure to ethanol >1000 ppm may cause headache, drowsiness, lassitude, appetite loss. Persons with chronic respiratory or skin disease are at increased risk with prolonged and/or repeated contact. |
| | Treatment | Same as above under First Aid |
| 5.0 Fire Fighting Measures | | |
| 5.1 | Suitable extinguishing media | Use dry chemical, alcohol foam, or carbon dioxide. Water may be ineffective, but should be used to keep fire-exposed containers cool. |
| 5.2 | Extinguishing media to avoid | Water may be ineffective, but will keep fire-exposed containers cool. |
| 5.3 | Special exposure hazards in a fire | Carbon monoxide, carbon dioxide from incomplete combustion |
| 5.4 | Special protective equipment for fire-fighters | Self-contained breathing apparatus. |
| 6.0 Accidental Release Measures | | |
| 6.1 | Personal precautions. | Wear chemical splash goggles and gloves. |
| 6.2 | Environmental precautions | Avoid releasing large quantities into environment. |
| 6.3 | Method for clean up | For small quantities: Ventilate area. Wear safety glasses, lab coat, gloves. Wipe up with absorbent material (paper or cloth towels). Rinse |

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area of spill with water. Place all material in closed container away from heat, sparks, sun and oxidizers.

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| 7.0 | Handling and Storage | |
| 7.1 | Handling | For use by dental professionals only. Remove applicator tip and recap immediately after use. Keep material tightly capped in original container. Do not use in presence of ignition sources. Take same precautions when container is emptied, as residual product is hazardous. |
| 7.2 | Storage | Remove applicator tip after use. Keep tightly capped in original container. Store at cool room temperature in a well ventilated area. Avoid heat, sparks, direct sunlight, and oxidizing agents. Vapor may form flammable mixtures with air. |
| 7.3 | Specific uses | Dental drying agent |
| 8.0 | Exposure Controls / Personal Protection | |
| 8.1 | Exposure limit values | Ethanol: 1000 ppm. Acetone: 750 ppm |
| 8.2 | Exposure controls | |
| 8.2.1 | Occupational exposure controls | No special equipment or ventilation required under normal conditions of use in dental practice. For large quantities/prolonged exposure, use enclosure, local ventilation, dilution to reduce concentration below TLV. |
| 8.2.1.1 | Respiratory protection | No special requirements under normal conditions of use. Good general ventilation is sufficient to control any airborne vapors. |
| 8.2.1.2 | Hand protection | No special requirements other than surgical gloves. |
| 8.2.1.3 | Eye protection | No special requirements other than safety glasses. |
| 8.2.1.4 | Skin protection | No special requirements other than good hygiene and safety practices. |
| 8.2.1.5 | Other controls | Emergency eye wash fountain should be close by and maintained. Wash hands after use. Do not eat, drink or smoke. |
| 8.2.2 | Environmental exposure controls | Follow all government regulations. |
| 9.0 | Physical and Chemical Properties | |
| 9.1 | Appearance / Color | |
| 9.1.1 | Color | Pink liquid |
| 9.1.2 | Odor | Characteristic, sweet, ethanol odor |
| 9.2 | Important health, safety and environmental information | |
| 9.2.1 | pH | Not applicable |

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| 9.2.2 | Boiling point | Boiling Point: 173°F / 78.3°C |
| 9.2.3 | Flash point | 43°F / 6°C (Tag closed cup) |
| 9.2.4 | Ignition temperature | 423°C |
| 9.2.5 | Explosive properties | LEL: 3.3; UEL: 19 |
| 9.2.6 | Odor threshold | 159 ppm |
| 9.2.7 | Vapor pressure | 44.6 mm Hg / 59 mbar / Id: E |
| 9.2.8 | Specific gravity | 0.795 |
| 9.2.9 | Solubility in water | Complete |
| 9.2.10 | Partition coefficient | Not determined |
| 9.2.11 | Viscosity | Not determined |
| 9.2.12 | Vapor density | 1.59 |
| 9.2.13 | Evaporation rate | Not determined |

10.0 Stability and reactivity

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|------|----------------------------------|---|
| 10.1 | Conditions to avoid | Heat, sparks, open flame, any ignition source. |
| 10.2 | Materials to avoid | Acetyl chloride and a wide range of oxidizing agents. |
| 10.3 | Hazardous decomposition products | Carbon monoxide, carbon dioxide from incomplete combustion. |
| 10.4 | Further information | Stable if stored and used as directed. |

11.0 Toxicological information

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|------|--|--|
| 11.1 | Acute toxicity | Minimal health hazard under normal conditions of use in dental practice Ethanol: LD ₅₀ in young rats: 10.6 g/kg orally; LD ₅₀ in old rats: 7.06 g/kg orally. Acetone: LD ₅₀ in rats : 10.7 ml/kg orally |
| 11.2 | Irritation and corrosiveness | May cause irritation/redness of eyes or skin on contact. May cause irritation of respiratory tract if inhaled. |
| 11.3 | Sensitization | Not applicable. |
| 11.4 | Sub-acute, sub-chronic and prolonged toxicity | No chronic health hazard under normal conditions of use. |
| 11.5 | Carcinogenicity, Mutagenicity, Reproductive Toxicity | Not a carcinogen under normal conditions of use. Large quantities, ingested over time, may be carcinogenic or a cause of Fetal Alcohol Syndrome. IARC has reported a relationship between habitual drinking of significant quantities of alcoholic beverages and cancer of oral cavity, pharynx, esophagus, liver. |

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| 11.6 | Empirical data | None available |
| 11.7 | Clinical experience | A typical application of <i>Dry-Rite</i> is a drop or two applied to the tooth surface and evaporated off. <i>Dry-Rite</i> and other alcohol-based drying agents have been used in dentistry for decades with no reported problems. |

12.0 Ecological Information

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|------|-------------|--|
| 12.1 | Ecotoxicity | Follow good work practices and government regulations. Avoid release into environment. |
|------|-------------|--|

13.0 Disposal Considerations

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|------|-------------|---|
| 13.1 | Regulations | Follow all local and national government regulations in disposing material or contaminated packaging. |
|------|-------------|---|

14.0 Transport Information

| | | |
|------|----------------|---------------|
| 14.1 | UN Number | 1170 |
| 14.2 | Technical name | Ethyl alcohol |
| 14.3 | Packing group | II |
| 14.4 | IATA class | 3 |

15.0 Regulatory Information

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|--------|----------------------------------|--|
| 15.1 | EU Regulations | <i>Dry-Rite</i> is a Class I Medical Device under the Medical Devices Directive 93/42/EEC. |
| 15.2 | Information on the warning label | Warning! Flammable. |
| 15.2.1 | Hazard symbol | F, Xi |
| 15.2.2 | Hazardous ingredients | Ethyl alcohol; Acetone (denaturant) |
| 15.2.3 | Risk phrases | R11: Highly flammable R36/ 37/38: Irritating to eyes, respiratory system and skin. R66: Repeated exposure may cause skin dryness or cracking. R67: Vapors might cause drowsiness or dizziness. |
| 15.2.4 | Safety phrases | S7/9: Keep container tightly closed and in a well ventilated area. S16: Keep away from sources of ignition. S24/25: Avoid contact with skin and eyes. S26: In case of contact with eyes, rinse immediately with running water and seek medical advice. S28: After contact with skin, wash immediately with soap and running water. |

16.0 Other information

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16.1 List of relevant R phrases

R11: Highly flammable

R36/ 37/38: Irritating to eyes, respiratory system and skin.

R66: Repeated exposure may cause skin dryness or cracking.

R67: Vapors might cause drowsiness or dizziness.

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| 16.2 | Training advice | Pulpdent dental materials are to be used only by dental professionals who have been trained in their use. |
| 16.3 | Restrictions on use | Pulpdent dental materials are to be sold to and used 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) 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 Commission Regulation (EC) No. 1907/2006 (REACH). |
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