


**Safety Data Sheet**Trade Name: **PULPDENT SPARKLE DIAMOND POLISHING PASTE**

| <b>1.0 Commercial Product Name and Supplier</b> |   |                         |                        |                         |                |   |      |         |   |      |                 |   |      |
|---|---|-------------------------|------------------------|-------------------------|----------------|---|------|---------|---|------|-----------------|---|------|
| 1.1   | Commercial product name / designation<br><i>Sparkle Diamond Polishing Paste</i>   |                         |                        |                         |                |   |      |         |   |      |                 |   |      |
| 1.2   | Application / Use<br>Dental material for use by dental professional only.   |                         |                        |                         |                |   |      |         |   |      |                 |   |      |
| 1.2.2   | SIC<br>851 Human health activity  |                         |                        |                         |                |   |      |         |   |      |                 |   |      |
| 1.2.3   | Use Category<br>55  |                         |                        |                         |                |   |      |         |   |      |                 |   |      |
| 1.3   | Manufacturer<br><b>Pulpdent Corporation</b><br>80 Oakland Street, Watertown, 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<br>1-800-535-5053 (24 Hour / USA)  |                         |                        |                         |                |   |      |         |   |      |                 |   |      |
| 1.5   | Authorized European Representative<br>Advena Limited<br>Tower Business Centre, 2nd Floor,<br>Tower Street,<br>Swatar, BKR 4013 Malta  |                         |                        |                         |                |   |      |         |   |      |                 |   |      |
|   | UK Responsible Person<br>Advena Limited<br>Pure Offices, Plato Close<br>Warwick, CV34 6WE United Kingdom  |                         |                        |                         |                |   |      |         |   |      |                 |   |      |
| <b>2.0 Hazards Identification</b>               |   |                         |                        |                         |                |   |      |         |   |      |                 |   |      |
| 2.1   | Classification<br>Irritant  |                         |                        |                         |                |   |      |         |   |      |                 |   |      |
| 2.1.1   | Classification according to Regulation (EC)<br>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>Eye irritation</td> <td>2</td> <td>H319</td> </tr> <tr> <td>STOT SE</td> <td>3</td> <td>H335</td> </tr> <tr> <td>Skin irritation</td> <td>2</td> <td>H315</td> </tr> </tbody> </table>  | <u>Hazard Class</u>     | <u>Hazard Category</u> | <u>Hazard Statement</u> | Eye irritation | 2 | H319 | STOT SE | 3 | H335 | Skin irritation | 2 | H315 |
| <u>Hazard Class</u>                             | <u>Hazard Category</u>  | <u>Hazard Statement</u> |                        |                         |                |   |      |         |   |      |                 |   |      |
| Eye irritation                                  | 2   | H319                    |                        |                         |                |   |      |         |   |      |                 |   |      |
| STOT SE   | 3   | H335                    |                        |                         |                |   |      |         |   |      |                 |   |      |
| Skin irritation                                 | 2   | H315                    |                        |                         |                |   |      |         |   |      |                 |   |      |
| 2.1.2   | Classification according to Directive 67/548/EEC<br>Irritant; Xi; R 36/37/38 (See SECTION 16 for full text of risk phrases)   |                         |                        |                         |                |   |      |         |   |      |                 |   |      |
| 2.2   | <b>GHS Label Elements</b><br>Hazard Pictograms<br><br>Signal Word: <b>WARNING</b><br><b>Restricted to use by dental professional only.</b><br><b>Hazard Statements</b><br>H319: Eye irritation. 2. May cause eye irritation.<br>H335: STOT SE. 3. May cause respiratory irritation.<br>H315: Skin irritation. 2. May cause skin irritation.<br><b>Precautionary Statements</b><br>P261: Avoid breathing vapor.<br>P280: Wear protective gloves and eye protection<br>P305+P351: If in eyes, rinse cautiously with water for several minutes.<br>P337+P313: If eye irritation persists, get medical advice/attention.<br>P302+P352: If on skin, wash with plenty of soap and water. |                         |                        |                         |                |   |      |         |   |      |                 |   |      |
| <b>3.0 Composition</b>                          |   |                         |                        |                         |                |   |      |         |   |      |                 |   |      |
| 3.1   | Chemical characterization of the preparation<br>Diamond powder in a cellulose matrix  |                         |                        |                         |                |   |      |         |   |      |                 |   |      |

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## 3.2 Hazardous ingredients

| CAS Number    | Name of the Ingredient | Concentration | Classification per 67/548/EEC | Classification per Regulation (EC) No.1272/2008 (CLP)                  |
|---------------|------------------------|---------------|-------------------------------|--|
| Not available | Diamond powder         | 5-6%          | Xi (Irritant)<br>R36/37/38    | Eye irritation, 2, H319<br>STOT SE 3, H335<br>Skin irritation, 2, H315 |

**4.0 First Aid Measures**

|     |                                  |  |
|-----|----------------------------------|--|
| 4.1 | General Information              | Minimal health hazard under normal conditions of use. May be irritating to eyes, respiratory system and skin on contact. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty. |
| 4.2 | Inhalation                       | Move to fresh air. If necessary, administer oxygen / artificial respiration; seek medical attention.   |
| 4.3 | Skin Contact                     | Take off contaminated clothing; wash skin with soap and water.   |
| 4.4 | Eye Contact                      | Keep eyelids apart; flush with running water for 15+ minutes. Get medical attention if irritation persists.  |
| 4.5 | Ingestion                        | Rinse mouth with water. Do not induce vomiting. Get immediate medical attention. May be irritating to mucous membranes. Never give anything by mouth to an unconscious person.   |
| 4.6 | Precautions for first responders | Wear eye and skin protection.  |
| 4.7 | Information for physicians       |  |
|     | Symptoms                         | Irritation or redness in eyes, throat or on skin.  |
|     | Hazards                          | May be irritating to eyes, respiratory system and skin.  |
|     | Treatment                        | As above under First Aid.  |

**5.0 Fire Fighting Measures**

|     |  |   |
|-----|--|---|
| 5.1 | Suitable extinguishing media                   | Carbon dioxide, dry chemical, alcohol foam, or water fog. Water spray may be used to keep fire exposed containers cool. |
| 5.2 | Extinguishing media to avoid                   | None  |
| 5.3 | Special exposure hazards in a fire             | None  |
| 5.4 | Special protective equipment for fire-fighters | A self-contained breathing apparatus  |

**6.0 Accidental Release Measures**

|     |                           |   |
|-----|---------------------------|---|
| 6.1 | Personal precautions      | Ventilate area. Wear safety glasses, gloves, and lab coat.  |
| 6.2 | Environmental precautions | Contain spilled material. Follow all government regulations.  |
| 6.3 | Method for clean up       | Absorb or wipe up spill with paper towels or cloths. Collect for disposal in a covered container. Wash area of spill with soap and water. |

**7.0 Handling and Storage**

|     |               |  |
|-----|---------------|--|
| 7.1 | Handling      | For use only by dental professionals. Follow good hygiene practices. Do not smoke, eat or drink while using. Cap container immediately after use.  |
| 7.2 | Storage       | Store tightly capped in original container at cool room temperature (<25°C). Avoid temperature extremes (>27°C/80°F, <5°C/40°F). Shelf life for unopened product is two years from date of manufacture, provided that the material has been stored properly. |
| 7.3 | Specific uses | Dental material used to polish porcelain, gold, composite and metal.   |

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| <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 required under normal conditions of use.                               |
| 8.2.1.1  | Respiratory protection                                 | Good general ventilation is sufficient to control any airborne vapors.                      |
| 8.2.1.2  | Hand protection  | No special requirements other than usual surgical gloves.                                   |
| 8.2.1.3  | Eye protection   | No special requirements other than usual safety glasses.                                    |
| 8.2.1.4  | Skin protection  | Good personal hygiene and safety practices; wearing a lab coat.                             |
| 8.2.1.5  | Other controls   | Emergency eye wash fountain. Wash hands after use.  |
| 8.2.2  | Environmental exposure controls                        | Follow all government regulations.  |
| <b>9.0 Physical and Chemical Properties</b>        |  |   |
| 9.1  | Characteristics  |   |
| 9.1.1  | Appearance /Color / Physical state                     | Light grey paste  |
| 9.1.2  | Odor   | Peppermint  |
| 9.2  | Important health, safety and environmental information |   |
| 9.2.1  | pH   | Not determined  |
| 9.2.2  | Boiling point  | Not determined  |
| 9.2.3  | Flash point  | Not determined  |
| 9.2.4  | Flammability (solid, gas)                              | Not applicable  |
| 9.2.5  | Explosive properties                                   | Not applicable  |
| 9.2.6  | Oxidizing properties                                   | Not determined  |
| 9.2.7  | Vapor pressure   | Not determined  |
| 9.2.8  | Specific gravity                                       | 1.180   |
| 9.2.9  | Solubility in water                                    | Cellulose matrix: soluble<br>Diamond powder: insoluble                                      |
| 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  |
| <b>10.0 Stability and reactivity</b>               |  |   |
| 10.1   | Conditions to avoid                                    | Avoid temperature extremes (>80°F / 27°C, <40°F / 5°C), sources of ignition, contamination. |
| 10.2   | Materials to avoid                                     | Strong oxidizers and alkaline solutions   |
| 10.3   | Hazardous decomposition products                       | Strong oxidizers and alkaline solutions may liberate isopropylamine.                        |
| 10.4   | Further information                                    | None  |
| <b>11.0 Toxicological information</b>              |  |   |

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|             |  |   |
|-------------|--|---|
| 11.1        | Acute toxicity                                       | Not toxic. Minimal health hazard in the quantities present in this product and under normal conditions of use.  |
| 11.2        | Irritation and corrosiveness                         | May be irritating to eyes, mucous membranes or skin on contact or with prolonged exposure.  |
| 11.3        | Sensitization  | Not sensitizing   |
| 11.4        | Sub-acute, sub-chronic and prolonged toxicity        | Prolonged exposure may cause eye and respiratory irritation.  |
| 11.5        | Carcinogenicity, Mutagenicity, Reproductive Toxicity | None known  |
| 11.6        | Empirical data                                       | Not available   |
| 11.7        | Clinical experience                                  | Sparkle has been sold on the domestic and international market for > 20 years with no reports of adverse events.  |
| <b>12.0</b> | <b>Ecological Information</b>                        |   |
| 12.1        | Ecotoxicity  | Follow all government regulations.  |
| <b>13.0</b> | <b>Disposal Considerations</b>                       |   |
| 13.1        | Regulations  | Follow all local and national government regulations in disposing material or contaminated packaging.   |
| <b>14.0</b> | <b>Transport Information</b>                         |   |
| 14.1        | Restrictions   | None. Not regulated.  |
| <b>15.0</b> | <b>Regulatory Information</b>                        |   |
| 15.1        | EU   | Class I medical devices under MDR 93/42/EEC.  |
| 15.2        | US FDA   | Class I medical device  |
| 15.3        | Health Canada  | Class I medical device  |
| <b>16.0</b> | <b>Other information</b>                             |   |
| 16.1        | List of relevant R phrases                           | R36/37/38: Irritating to eyes, respiratory system and skin.   |
| 16.2        | Hazard Statements                                    | H319: Eye irritation. Hazard category 2.<br>H335: Specific Target Organ Toxicity - Single exposure; hazard category. 3. Respiratory tract irritation.<br>H315: Skin irritation. Hazard category 2.  |
| 16.3        | Precautionary Statements                             | P261: Avoid breathing vapor.<br>P280: Wear protective gloves and eye protection<br>P305 + P351: If in eyes, rinse cautiously with water for several minutes.<br>P337 + P313: If eye irritation persists, get medical advice/attention.<br>P302 + P352: If on skin, wash with plenty of soap and water.                            |
| 16.4        | Restrictions on use                                  | Pulpdent products are to be sold to and used 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 |

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|      |   |   |
|------|---|---|
|      |   | 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 |
| 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 (EC) No. 1907/2006 (REACH). Specifically Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified.   |

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