

Safety Data Sheet

Trade Name: **PULPDENT SPARKLE DIAMOND POLISHING PASTE**

1.0 Commercial Product Name and Supplier				
1.1	Commercial product name / designation		Sparkle Diamond Polishing Paste	
1.2	Application / Use		Dental material for use by dental professional only.	
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		Telephone: 1 617 926-6666	
	P.O. Box 780		Fax: 1 617 926-6262	
	Watertown, MA 02472 USA		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.		Tel: 07989 407479 / Fax: 01256 350330	
	54 Mayfield Ridge		Email: s.williams5@btconnect.co.uk	
	Hatch Warren, Basingstoke, RG22 4RS UK			
2.0 Hazards Identification				
2.1	Classification		Irritant	
2.1.1	Classification according to Regulation (EC) No 1272/2008 [CLP]		<u>Hazard Class</u>	<u>Hazard Category</u>
			Eye irritation	2
			STOT SE	3
			Skin irritation	2
2.1.2	Classification according to Directive 67/548/EEC (See SECTION 16 for full text of risk phrases)		Irritant; Xi; R 36/37/38	
2.2	Label Elements			
	Labeling according to Regulation (EC) No 1272/2008 [CLP]			
	Hazard Pictograms			
				
	Signal Word: WARNING			
	Restricted to use by dental professional only.			
	Hazard Statements			
	H319: Eye irritation. 2. May cause eye irritation.			
	H335: STOT SE. 3. May cause respiratory irritation.			
	H315: Skin irritation. 2. May cause skin irritation.			
	Precautionary Statements			
	P261: Avoid breathing vapor.			
	P280: Wear protective gloves and eye protection			

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P305+P351: If in eyes, rinse cautiously with water for several minutes.

P337+P313: If eye irritation persists, get medical advice/attention.

P302+P352: If on skin, wash with plenty of soap and water.

3.0	Composition				
3.1	Chemical characterization of the preparation		Diamond powder in a cellulose matrix		
3.2	Hazardous ingredients				
	CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1278/2008 (CLP)
	Not available	Diamond powder	5-6%	Xi (Irritant) R36/37/38	Eye irritation, 2, H319 STOT SE 3, H335 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.		

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6.2	Environmental precautions	Contain spilled material. Follow all government regulations.
6.3	Method for clean up	Absorb or wipe up spill with suitable material (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	Keep container tightly closed. Store in original container at cool room temperature (<25°C). Avoid extremes of temperature (>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.

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 under normal conditions of use of this product in the quantity provided.
8.2.1.1	Respiratory protection	None required. 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	No special requirements. Good personal hygiene and safety practices and wearing a lab coat should protect dental staff from unnecessary exposure to material.
8.2.1.5	Other controls	Emergency eye wash fountain. Wash hands after use.
8.2.2	Environmental exposure controls	Follow all government regulations.

9.0 Physical and Chemical Properties

9.1	Appearance / Color	
9.1.1	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

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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 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
10.0	Stability and reactivity	
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
11.0	Toxicological information	
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. During that time there have been no reports of adverse events, no recalls, and no significant complaints.
12.0	Ecological Information	
12.1	Ecotoxicity	Follow all government regulations.
13.0	Disposal Considerations	
13.1	Regulations	Follow all local and national government regulations in disposing material or contaminated packaging.

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14.0	Transport Information	
14.1	Restrictions	None. Not regulated.
15.0	Regulatory Information	
15.1	EU	Class I medical devices under MDD 93/42/EEC.
15.2	US FDA	Class I medical device
15.3	Health Canada	Class I medical device
16.0	Other information	
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. H335: Specific Target Organ Toxicity - Single exposure; hazard category. 3. Respiratory tract irritation. H315: Skin irritation. Hazard category 2.
16.3	Precautionary Statements	P261: Avoid breathing vapor. P280: Wear protective gloves and eye protection P305 + P351: If in eyes, rinse cautiously with water for several minutes. P337 + P313: If eye irritation persists, get medical advice/attention. 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 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 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.