

Safety Data SheetTrade Name: **PerioCare**

1.0 Commercial Product Name and Supplier		
1.1	Commercial product name / designation	<i>PerioCare</i>
1.2	Application / Use	Periodontal dressing
1.2.2	SIC	851 Human health activity
1.2.3	Use Category	55
1.3	Manufacturer	
	Pulpdent Corporation 80 Oakland Street 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	Advena Limited Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta
2.0 Hazards Identification		
2.1	Classification	
2.1.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Not hazardous
2.1.2	Classification according to Directive 67/548/EEC	Not hazardous
2.2	GHS Label Elements	
	Restricted to use by dental professional only	
3.0 Composition		
3.1	Chemical characterization of the preparation	Paste: metal oxides in vegetable oil Gel: Rosins suspended in fatty acid.
3.2	Hazardous Ingredients	None in this formulation
4.0 First Aid Measures		
4.1	General Information	Non-hazardous material Material may cause mild, mechanical eye irritation. 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.
4.5	Ingestion	Non-toxic
4.6	Precautions for first responders	Wear safety glasses and gloves.
4.7	Information for physicians	
	Symptoms	Mild irritation/redness in eyes.
	Hazards	Mild, mechanical eye irritation

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Treatment	Same as above under First Aid.
5.0 Fire Fighting Measures	
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.
6.0 Accidental Release Measures	
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	Wipe up spill with suitable material (paper towels or disposable 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 trained dental professionals. Follow good hygiene practices.
7.2 Storage	Store product tightly capped in original containers at cool room temperature (< 25°C). Shelf life for unopened product is two years from date of manufacture, provided proper storage.
7.3 Specific uses	Periodontal dressing
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 under normal conditions of use
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	Paste: Thick, pink paste; Gel: Thick, yellow-tinted gel.
9.1.2 Odor	Characteristic
9.2 Important health, safety and environmental information	
9.2.1 pH	Not determined
9.2.2 Boiling point	Not determined

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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	Paste: 1.90; Gel: 1.05
9.2.9	Solubility in water	Slight
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	Nil
10.0	Stability and reactivity	
10.1	Conditions to avoid	None known
10.2	Materials to avoid	None known
10.3	Hazardous decomposition products	None
10.4	Further information	Stable material
11.0	Toxicological information	
11.1	Acute toxicity	Not toxic.
11.2	Irritation and corrosiveness	May be irritating to eyes 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	PerioCare has been used safely and effectively for post-surgical tissue management for more than 30 years with no reports of device failure, allergic reaction or deterioration of the soft tissue under the dressing..
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.
14.0	Transport Information	
14.1	Restrictions	None. Not regulated by IATA.
15.0	Regulatory Information	
15.1	EU	Class IIa medical device under the MDD 93/42/EEC.
15.2	US FDA	Class II medical device

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15.3 Health Canada Class I medical device

16.0 Other information

16.1	List of relevant R phrases	None
16.2	Hazard Statements	None
16.3	Precautionary Statements	None
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) 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 the 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.