Safety Data Sheet

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

Trade Name***: PULPDENT HardCore™***

1.0	**Commercial Product Name and Supplier**	
1.1	Commercial product name / designation	***HardCore™ Core Build-Up Material***
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 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	Irritant.
2.2	Adverse human health effects	May be irritating to eyes, respiratory system and skin. Do not inhale vapors. May cause sensitization by skin contact.
3.0	**Composition**	
3.1	Chemical characterization of the preparation:	Methacrylate ester monomers in two-part, glass-filled, dual-cure paste.

3.2 Hazardous ingredients

CAS Number / EC Number	Name of the Ingredient	Concentration	Warning symbol, R phrases
----------	Uncured methacrylate ester monomers	55-60%	Xi (Irritant), R36/37/38, R43
112945-52-5	Amorphous silica	5%	Xi (Irritant), R36/37/38

4.0 First Aid Measures

4.1	General Information	May be irritating to eyes, respiratory system and skin. Do not inhale vapors. May cause sensitization by skin 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 and seek medical attention.
4.3	Skin Contact	Take off contaminated clothing. Wash skin thoroughly with soap and water for 15 minutes.
4.4	Eye Contact	Keep eyelids apart and flush with running water for 15+ minutes. Get medical attention.
4.5	Ingestion	Rinse mouth with water. Do not induce vomiting. Get immediate medical attention. May be irritating to mucous membranes.
4.6	Precautions for first responders	Ventilate the area. 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. May cause sensitization by skin contact.
	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	Do not use direct water stream
5.3	Special exposure hazards in a fire	Heat may cause polymerization with rapid release of energy.
5.4	Special protective equipment for fire-fighters	A self-contained breathing apparatus should be worn by fire fighting personnel. Cool exposed containers with water spray to prevent polymerization under fire conditions.
6.0	**Accidental Release Measures**	
6.1	Personal precautions.	Ventilate area. Wear gloves, lab coat and safety glasses.
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 alcohol or soap and water.
7.0	**Handling and Storage**	
7.1	Handling	For use only by dental professionals trained in their use. Follow good hygiene practices. Do not smoke, eat or drink while using. Remove applicator tip and cap syringe immediately after use. Avoid cross-contamination of two-part products. Keep light cure and dual cure materials shaded from intense light sources.
7.2	Storage	Keep containers tightly closed. Store product in original container at cool room temperature (< 25°C) and in a dry, well ventilated area. Avoid direct, strong light, sources of ignition and extremes of temperature. Shelf life for unopened product is two years from date of manufacture, provided that the material has been stored properly.
7.3	Specific uses	Professional dental material
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 from uncured material.
8.2.1.2	Hand protection	No special requirements. The usual surgical gloves worn

		by dental staff will limit contact with uncured material.
8.2.1.3	Eye protection	No special requirements other than the usual safety glasses worn by dental staff.
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 uncured material.
8.2.1.5	Other controls	Emergency eye wash fountain should be available. Wash hands after use.
8.2.2	Environmental exposure controls	Cure material before disposing.

9.0 Physical and Chemical Properties

9.1	Appearance / Color	
9.1.1	Color / Physical state	Two pastes, one white and one ivory.
9.1.2	Odor	Faint, characteristic
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	< 1 mm Hg
9.2.8	Specific gravity	2.08
9.2.9	Solubility in water	Nil
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	Heat (> 38°C), light, cross-contamination.
10.2	Materials to avoid	Reducing and oxidizing agents, peroxides, amines.
10.3	Hazardous decomposition products	Under fire conditions and with amounts far greater than that supplied in this product, hazardous polymerization may occur with heat build up and release of carbon monoxide, carbon dioxide, and oxides of nitrogen.
10.4	Further information	Polymerization will occur when light-cured material is exposed to direct light and when self-cure or dual-cure material is cross-contaminated.

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	May be sensitizing. Prolonged or frequent skin contact may cause allergic skin reactions in some susceptible individuals.
11.4	Sub-acute, sub-chronic and prolonged toxicity	Prolonged and/or frequent skin contact may cause allergic skin reactions in susceptible individuals. Prolonged exposure to large amounts (more than in this product) of this material may cause eye and respiratory irritation.
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known
11.6	Empirical data	Not available
11.7	Clinical experience	According to the US National Institute of Health Technology Assessment Conference on *Effects and Side-Effects of Dental Restorative Materials*: “General usage of these materials over about 20 years indicates a high benefit-to-risk ratio...both composites and glass ionomers are relatively trouble-free. There is no evidence of short-term or long-term risk...There is no suspicion of any problems after virtually billions of procedures in the

		United States."
12.0	**Ecological Information**	
12.1	Ecotoxicity	Avoid release of uncured material into the environment. To the best of our knowledge, polymerized material is inert. No other information is available.
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	None. Not regulated.
15.0	**Regulatory Information**	
15.1	EU Regulations	HardCore is a Class IIA Medical Device under the Medical Devices Directive 93/42/EEC.
15.2	Information on the warning label	
15.2.1	Hazard symbol	Xi
15.2.2	Hazardous ingredient	Uncured methacrylate ester monomers
15.2.3	Risk phrases	R36/37/38, Irritating to eyes, respiratory system and skin. R43, Sensitizing by skin contact.
15.2.4	Safety phrases	S3/9/14/49: Keep only in the original container, in a cool well-ventilated place, away from intense light, sources of ignition and moisture. S24/25: Avoid contact with skin and eyes.
16.0	Other information	
16.1	List of relevant R phrases	R36/37/38, Irritating to eyes, respiratory system and skin. R43, Sensitizing by skin contact.
16.2	Training advice	Pulpdent products are for use by dental professionals only.
16.3	Restrictions on use	Pulpdent products are for use 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) US 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 Regulation (EC) No. 1907/2006 (REACH).