


Safety Data Sheet

Trade Name: *HardCore™ Core Build-up Material*

1.0 Commercial Product Name and Supplier																		
1.1	Commercial product name / designation <i>HardCore</i> Core Build-Up Material																	
1.2	Application / Use Core Build-Up Material for use by dental professional only.																	
1.2.2	SIC 851 Human health activity																	
1.2.3	Use Category 55																	
1.3	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: s.williams5@btconnect.co.uk																	
2.0 Hazards Identification																		
2.1	Classification																	
2.11	<table border="1"> <thead> <tr> <th>Classification according to Regulation (EC) No 1272/2008 [CLP]</th> <th>Hazard Class</th> <th>Hazard Category</th> <th>Hazard Statement</th> </tr> </thead> <tbody> <tr> <td rowspan="4"></td> <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> <tr> <td>Skin sensitization</td> <td>1</td> <td>H317</td> </tr> </tbody> </table>	Classification according to Regulation (EC) No 1272/2008 [CLP]	Hazard Class	Hazard Category	Hazard Statement		Eye irritation	2	H319	STOT SE	3	H335	Skin irritation	2	H315	Skin sensitization	1	H317
Classification according to Regulation (EC) No 1272/2008 [CLP]	Hazard Class	Hazard Category	Hazard Statement															
	Eye irritation	2	H319															
	STOT SE	3	H335															
	Skin irritation	2	H315															
	Skin sensitization	1	H317															
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 - 43																	
2.2	GHS Label Elements 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.																	
	H317: Sensitization. 1. May cause an allergic skin reaction.																	
	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.																	

Safety Data SheetTrade Name: *HardCore™ Core Build-up Material*

P333+P313: If irritation or rash occurs, get medical advice/attention.

P410+P411: Protect from sunlight. Store at temperature not exceeding 27°C / 80°F.

3.0 Composition				
3.1	Chemical characterization of the preparation: Glass filled, resin-based, dual-cure core-build-up material in two parts.			
3.2	Hazardous ingredients			
	CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC
	Proprietary	Uncured methacrylate resin mixture	20-25%	Irritant; Xi R 3637//38 - 43
	112945-52-5	Amorphous, fumed silica	< 5.0%	Irritant; Xi, R 36/37/38
				Classification per Regulation (EC) No.1278/2008 (CLP). Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317 Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315
4.0 First Aid Measures				
4.1	Special Instructions	May be irritating to eyes, respiratory system and skin. Avoid contact with eyes 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 artificial respiration and seek medical attention for difficulty breathing.		
4.3	Skin Contact	Take off contaminated clothing. Wash skin thoroughly with soap and water.		
4.4	Eye Contact	Keep eyelids apart and flush with running water for 15+ minutes. Get medical attention for persistent irritation.		
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 gloves to prevent skin contact and safety glasses if splash is a possibility.		
4.7	Information for physician			
	Symptoms	Irritation or redness in eyes and on skin.		
	Hazards	May be irritating to eyes, respiratory system and skin. Possible sensitization with prolonged or repeated skin contact.		
	Treatment	Same 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.		

Safety Data SheetTrade Name: *HardCore™ Core Build-up Material*

5.4 Special protective equipment for fire-fighters A self-contained breathing apparatus should be worn by firefighting 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 the use of dental materials. Follow good hygiene practices. Do not smoke, eat or drink while using. Cap product immediately after use. Keep light-cured materials shaded from intense light. Not an aerosol or dust hazard.
 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, extremes of temperature (>27°C/80°F, <5°C/40°F) and cross-contamination. 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

8.0 Exposure Controls / Personal Protection

8.1 Exposure limit values Amorphous, fumed silica [CAS No. 112945-52-5]
 PEL/TLV: Not established; PEL/TLV: 6 mg/m³ / 10 mg/m³
 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. No unincorporated powder. Good general ventilation is sufficient to control any airborne vapors from uncured material.
 8.2.1.2 Hand protection No special requirements. Usual surgical gloves worn by dental staff will limit contact with uncured material.
 8.2.1.3 Eye protection No special requirements other than safety glasses.
 8.2.1.4 Skin protection No special requirements. Good personal hygiene and safety practices and wearing a lab coat will prevent contact with uncured material.
 8.2.1.5 Other controls Emergency eye wash fountain should be close. Wash hands after use.
 8.2.2 Environmental exposure controls Cure material before disposing.

9.0 Physical and Chemical Properties

9.1	Appearance / Color	<u>Base</u> Pale yellow thick paste	<u>Catalyst</u> Off-white thick paste
9.1.2	Odor	Faint, characteristic	

Safety Data SheetTrade Name: *HardCore™ Core Build-up Material*

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	2.080
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	Temperature > 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 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 with cross-contamination and when light-cured material is exposed to direct light.

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

Safety Data SheetTrade Name: *HardCore™ Core Build-up Material*

11.7	Clinical Experience	HardCore has been on the market in the US and internationally for more than 15 years. There have been no reports of adverse events.
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. Cure material before disposing. To the best of our knowledge, polymerized material is inert.
14.0	Transport Information	
14.1	Restrictions	None. Not regulated.
15.0	Regulatory Information	
15.1	EU	Class IIa medical device under MDD 93/42/EEC.
15.2	US FDA	Class II medical device
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	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. H317: Skin Sensitization. Hazard category 1.
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. P333 + P313: If irritation or rash occurs, get medical advice / attention. P410 + P411: Protect from sunlight. Store at temperature not exceeding 27°C / 80°F.
16.4	Restrictions on use	HardCore is for use by dental professionals only.

Safety Data Sheet

Trade Name: *HardCore™ Core Build-up Material*

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
16.6	Information which has been added, deleted or revised.	This Safety Data Sheet has been revised to meet the GHS SDS format and the requirements of Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH). Specifically Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified.
