


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

1.0 Commercial Product Name and Supplier																
1.1	Commercial product name / designation <i>HardCore Core Build-Up Material</i>															
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 Advena Ltd. Pure Offices, Plato Close Warwick, CV34 6WE United Kingdom															
2.0 Hazards Identification																
2.1	Classification															
2.11	Classification according to Regulation (EC) 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> <tr> <td>Skin sensitization</td> <td>1</td> <td>H317</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	Skin sensitization	1	H317
<u>Hazard Class</u>	<u>Hazard Category</u>	<u>Hazard Statement</u>														
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 Irritant (Xi); R 36/37/38 – 43 (See SECTION 16 for full text of risk phrases)															
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.															
	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.															

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

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															
	<table border="1"> <thead> <tr> <th>CAS Number</th> <th>Name of the Ingredient</th> <th>Concentration</th> <th>Classification per 67/548/EEC</th> <th>Classification per Regulation (EC) No.1272/2008 (CLP).</th> </tr> </thead> <tbody> <tr> <td>Proprietary</td> <td>Uncured methacrylate resin mixture</td> <td>20-25%</td> <td>Irritant; Xi R 3637//38 - 43</td> <td>Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317</td> </tr> <tr> <td>112945-52-5</td> <td>Amorphous, fumed silica</td> <td>< 5.0%</td> <td>Irritant; Xi, R 36/37/38</td> <td>Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315</td> </tr> </tbody> </table>	CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1272/2008 (CLP).	Proprietary	Uncured methacrylate resin mixture	20-25%	Irritant; Xi R 3637//38 - 43	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317	112945-52-5	Amorphous, fumed silica	< 5.0%	Irritant; Xi, R 36/37/38	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315
CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1272/2008 (CLP).												
Proprietary	Uncured methacrylate resin mixture	20-25%	Irritant; Xi R 3637//38 - 43	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317												
112945-52-5	Amorphous, fumed silica	< 5.0%	Irritant; Xi, R 36/37/38	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 and safety glasses															
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.															
5.4	Special protective equipment for fire-fighters Self-contained breathing apparatus.															
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															

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

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 alcohol or soap and water

7.0 Handling and Storage

7.1 Handling Follow good hygiene practices. Cap product immediately after use. Keep light-cured materials shaded from intense light.

7.2 Storage Store tightly capped in original container at cool room temperature (<25°C). Avoid direct, strong light, ignition sources, temperature extremes (>27°C/80°F, <5°C/40°F), 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: 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

8.2.1.1 Respiratory protection Good general ventilation is sufficient to control any airborne vapors.

8.2.1.2 Hand protection Usual surgical gloves will limit contact with uncured material.

8.2.1.3 Eye protection Safety glasses.

8.2.1.4 Skin protection Good personal hygiene and safety practices; wear a lab coat

8.2.1.5 Other controls Emergency eye wash fountain should be close by. Wash hands after use.

8.2.2 Environmental exposure controls Cure material before disposing.

9.0 Physical and Chemical Properties

9.1 Characteristics

9.1.1 Appearance /Color / Physical state Base: Pale yellow thick paste Catalyst: Off-white thick paste

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 2.080

9.2.9 Solubility in water Nil

9.2.10 Partition coefficient Not determined

9.2.11 Viscosity Not determined

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

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 *For large amounts only:* Under fire conditions hazardous polymerization may occur with heat build up and release of carbon monoxide, carbon dioxide, 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 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 Used safely and effectively in the US and internationally for more than 15 years with 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.

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

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

16.2	Hazard Statements	R43, Sensitizing by skin contact 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.
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 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.
