

SAFETY DATA SHEETS

This SDS packet was issued with item:

075899224

The safety data sheets (SDS) in this packet apply to the individual products listed below. Please refer to invoice for specific item number(s).

075899208 075899216 075899232 075899240 075899257

80 Oakland Street
Watertown, MA 02472
USA

Pulpdent Corporation

Tel: 617 926 6666
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MATERIALS SAFETY DATA SHEET: KLEER™ VENEER

IDENTITY

Trade Name: KLEER™ VENEER
Chemical Description: Light-cured, glass-filled resin (No Bisphenol A)
Product Use: Dental material

SECTION I

Pulpdent Corporation
80 Oakland Street
Watertown, MA 02472 USA

Phone Numbers:
24 Hr. Emergency: 1-800-535-5053
Customer Service: 1-800-343-4342 / 1-617-926-6666

Date Prepared: January 1, 2009

SECTION II - HAZARDOUS INGREDIENTS

<i>Ingredients</i>	<i>CAS Number</i>	<i>PEL / TLV</i>
Acrylate resin mixture	Not established	Not established
DOT HAZARD CLASSIFICATION:	Not regulated.	
WHMIS CLASSIFICATION:	D-2 possible irritant	
NFPA HMIS RATING: HEALTH: 0	FLAMMABILITY: 0	REACTIVITY: 1

SECTION III - PHYSICAL / CHEMICAL CHARACTERISTICS

Specific Gravity: Solubility in water: nil
Odor Threshold: Not available
Appearance and Odor: Clear paste with slight, characteristic odor.

SECTION IV - FIRE AND EXPLOSION HAZARD DATA

Flash Point: Not established Flammable limits: Not established
Extinguishing Media: Carbon dioxide, dry chemical, alcohol foam, or water fog. Water spray to keep fire exposed containers cool.
Special Fire Fighting Procedures: Fire fighting personnel should wear a self-contained breathing apparatus. Cool exposed containers with water spray to prevent polymerization under fire conditions.
Hazardous Combustion Products: Hazardous polymerization with heat build up and release of carbon monoxide, carbon dioxide and oxides of nitrogen may occur under fire conditions.

SECTION V - REACTIVITY DATA

Stability: Stable
Conditions to avoid: Temperature > 37°C / 100°F, intense or direct light.
Incompatibility: Reducing and oxidizing agents.
Hazardous Decomposition Products: Carbon monoxide, carbon dioxide, oxides of nitrogen.
Hazardous Polymerization: None under normal conditions of use.
Conditions to avoid: Temperature > 37°C / 100°F, intense or direct light.

SECTION VI - HEALTH HAZARD DATA

Summary of Acute Hazards: Minimal health hazard under normal conditions of use in a dental practice. May be irritating to eyes, mucous membranes or skin. May be sensitizing with prolonged and/or repeated exposure.

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Route of Exposure

Inhalation

Eye Contact

Skin Absorption

Skin Contact

Ingestion

Signs & Symptoms

May be irritating to mucous membranes

May be irritating

Not applicable

Primary route of exposure. May be irritating

May be irritating to mucous membranes.

Summary of Chronic Hazards:

Carcinogenicity

Teratogenicity

Mutagenicity

Reproductive Toxicity

May be sensitizing with prolonged and/or repeated exposure.\

None known

None known.

None known.

None known.

Emergency First Aid Procedures:

Inhalation

Eye contact

Ingestion

Skin contact

Move to fresh air. Administer artificial respiration if needed, seek medical attention.

Flush eyes with copious amounts of water for 15 minutes. Seek medical attention.

Consult physician immediately.

Wash skin with soap and water for 15 minutes.

SECTION VII - PRECAUTIONS FOR SAFE HANDLING & USE

Handling and Storage Precautions: Store product in original container at cool room temperature (< 25°C) Avoid temperature extremes, intense light and moisture.

Release or Spill: Absorb / wipe up spill with suitable material; collect for disposal.

Waste Disposal Method: Follow all government regulations.

Other Precautions: None

SECTION VIII - CONTROL MEASURES

Respiratory Protection: None required under normal conditions of use.

Ventilation: No special ventilation recommended under anticipated conditions of normal use.

Protective Gloves: Recommended

Eye Protection: Safety glasses or goggles are recommended.

Other Protective Clothing or Equipment: Emergency eye wash fountain should be close by and maintained.

Work/Hygienic Practices: Wash hands after use.

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.

Safety Data Sheet

Trade Name: **PULPDENT KLEER-VENEER**

1.0 Commercial Product Name and Supplier				
1.1	Commercial product name / designation	KLEER-VENEER Light-Cure Veneer Cement		
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	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	Irritant.		
2.1.1	Classification according to Regulation (EC) No 1272/2008 [CLP]	<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 (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.			
	P304+340: If inhaled, remove victim to fresh air and keep at rest in a position comfortable for breathing.			
	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.			

Safety Data Sheet

Trade Name: **PULPDENT KLEER-VENEER**

3.0	Composition				
3.1	Chemical characterization of the preparation: Glass-filled, acrylate ester monomers, light-cure chemistry, in paste form.				
3.2	Hazardous ingredients				
	CAS Number	Name of the Ingredient	Concentration	Classification per 67/548/EEC	Classification per Regulation (EC) No.1272/2008 (CLP)
	Proprietary	Uncured acrylate ester monomers	55-60%	Xi (Irritant), R36/37/38, R43	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317
	112945-52-5	Silica, amorphous	< 5 %	Xi (Irritant) R 36/37/38	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315
4.0	First Aid Measures				
4.1	General Information		May be irritating to eyes, respiratory system and skin. Prolonged or repeated contact with acrylates may cause sensitization. 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 and/or artificial respiration and seek medical attention.		
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		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		Self-contained breathing apparatus		
6.0	Accidental Release Measures				
6.1	Personal precautions		Ventilate area. Wear safety glasses, gloves and lab coat.		
6.2	Environmental precautions		Contain spilled material. Follow all government regulations		

Safety Data Sheet

Trade Name: **PULPDENT KLEER-VENEER**

6.3 Method for clean up Wipe up spill with suitable material (paper towels or cloths). Collect for disposal in covered container. Wash spill site with alcohol or soap and water.

7.0 Handling and Storage

7.1 Handling Follow good hygiene practices. Remove applicator tip from syringe; cap 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, sources of ignition, extremes of temperature (>27°C/80°F, <5°C/40°F). Shelf life for unopened product that has been stored properly is 2 years from date of manufacture.

7.3 Specific uses 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.

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

8.2.1.2 Hand protection No special requirements other than the usual surgical gloves.

8.2.1.3 Eye protection No special requirements other than the usual safety glasses.

8.2.1.4 Skin protection Good personal hygiene, safety practices; lab coat

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. To the best of our knowledge, cured material is inert. Follow all government regulations.

9.0 Physical and Chemical Properties

9.1 Characteristics .

9.1.1 Appearance /Color / Physical state Clear, cream, pink or white 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 / 133 Pa / Id: B

9.2.8 Specific gravity 1.510

9.2.9 Solubility in water Nil

9.2.10 Partition coefficient Not determined

9.2.11 Viscosity Not determined

Safety Data Sheet

Trade Name: **PULPDENT KLEER-VENEER**

9.2.12	Vapor density	> 1
9.2.13	Evaporation rate	Not determined

10.0 Stability and reactivity

10.1	Conditions to avoid	Temperature extremes (>27°C/80°F, <5°C/40°F), direct light.
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 buildup, release of carbon monoxide, carbon dioxide, and oxides of nitrogen.
10.4	Further information	Light-cured materials exposed to direct light will polymerize.

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/frequent skin contact may cause allergic skin reactions in susceptible individuals. Prolonged exposure to large amounts of material may cause eye and respiratory irritation.
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known.
11.6	Empirical data	None available.
11.7	Clinical experience	Kleer-Veneer has been on the market for about 10 years, during which there have been no reports of adverse events.

12.0 Ecological Information

12.1	Ecotoxicity	To the best of our knowledge, polymerized material is inert. No other information is available.
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13.0 Disposal Considerations

13.1	Regulations	Polymerize before disposal. 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.
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15.0 Regulatory Information

15.1	EU	Class IIa medical devices under MDD 93/42/EEC.
15.2	US FDA	Class II medical devices
15.3	Health Canada	Class III medical devices

Safety Data SheetTrade Name: **PULPDENT KLEER-VENEER**

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. P304+340: If inhaled, remove victim to fresh air and keep at rest in a position comfortable for breathing. 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	Pulpdent products are 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.