

SAFETY DATA SHEETS

This SDS packet was issued with item:

075899224

The safety data sheets (SDS) in this packet apply to one or more components included in the items listed below. Items listed below may require one or more SDS. Please refer to invoice for specific item number(s).

075899208 075899216 075899232 075899240 075899257

Pulpdent Corporation

80 Oakland Street
Watertown, MA 02472
USA

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 | <p>Pulpdent Corporation 80 Oakland Street, P.O. Box 780 Watertown, MA 02472 USA</p> <p>Telephone: 1 617 926-6666 Fax: 1 617 926-6262 Email: Pulpdent@pulpdent.com</p> | | | | | | | | | | | | | | | | |
| 1.4 | Emergency Telephone Number | 1-800-535-5053 (24 Hour / USA) | | | | | | | | | | | | | | | | |
| 1.5 | Authorized European Representative | <p>Advena Ltd. Pure Offices, Plato Close Warwick, CV34 6WE United Kingdom</p> | | | | | | | | | | | | | | | | |
| 2.0 Hazards Identification | | | | | | | | | | | | | | | | | | |
| 2.1 | Classification | Irritant. | | | | | | | | | | | | | | | | |
| 2.1.1 | 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 (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 SheetTrade 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 SheetTrade 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 SheetTrade 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. |
|------|-------------|---|

13.0 Disposal Considerations

| | | |
|------|-------------|---|
| 13.1 | Regulations | Polymerize before disposal. 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 | 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. |