

Safety Data Sheet

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

Trade Name: **Kleer-Veneer™**

1.0 Commercial Product Name and Supplier													
1.1	Commercial product name / designation <i>Kleer-Veneer™</i>												
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. May cause sensitization by skin contact.												
3.0 Composition													
3.1	Chemical characterization of the preparation: Glass-filled, acrylate ester monomers with light-cure chemistry in paste form.												
3.2	Hazardous ingredients												
	<table border="1"> <thead> <tr> <th>CAS Number</th> <th>Name of the Ingredient</th> <th>Concentration</th> <th>Warning symbol, R phrases</th> </tr> </thead> <tbody> <tr> <td>Proprietary</td> <td>Uncured acrylate ester monomers</td> <td>55-60%</td> <td>Xi (Irritant), R 36/37/38 - 43</td> </tr> <tr> <td>112945-52-5</td> <td>Silica, amorphous</td> <td>< 5 %</td> <td>Xi (Irritant), R 36/37/38</td> </tr> </tbody> </table>	CAS Number	Name of the Ingredient	Concentration	Warning symbol, R phrases	Proprietary	Uncured acrylate ester monomers	55-60%	Xi (Irritant), R 36/37/38 - 43	112945-52-5	Silica, amorphous	< 5 %	Xi (Irritant), R 36/37/38
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112945-52-5	Silica, amorphous	< 5 %	Xi (Irritant), R 36/37/38										
4.0 First Aid Measures													
4.1	General Information May be irritating to eyes, respiratory system and skin. Do not inhale vapors. Avoid contact with eyes and skin. May cause sensitization by skin contact. Show this safety data sheet to medical personnel. Get												

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		medical attention in case of uncertainty.
4.2	Inhalation	Move to fresh air. If necessary, administer oxygen and/or artificial respiration. 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. 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. Cool exposed containers with water spray to prevent polymerization under fire conditions.
6.0	Accidental Release Measures	
6.1	Personal precautions.	Wear safety glasses, gloves and lab coat.
6.2	Environmental precautions	Avoid releasing large amounts of uncured material into the environment. Cured / set-up material is, to our knowledge, inert.
6.3	Method for clean up	Contain spilled material. 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	For use only by dental professionals. Follow good hygiene practices. Do not smoke, eat or drink while using. Avoid direct / strong light sources, extremes of temperature and contamination. Recap immediately after use.

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7.2 Storage Store in original container, tightly capped, at cool room temperature (< 25°C) and in a dry, well ventilated area. Avoid strong light, sources of ignition, extremes of temperature. Shelf life for unopened product properly stored is two 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 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 close by and maintained. 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

<u>Product</u>	<u>Description</u>
<i>Kleer-Veneer™ Clear</i>	Clear paste
<i>Kleer-Veneer™ Opaque Cream</i>	Off-white paste
<i>Kleer-Veneer™ Opaque Pink</i>	Pink paste
<i>Kleer-Veneer™ Opaque White</i>	White paste

9.1.2 Odor Faint, characteristic

9.2 Important health, safety and environmental information

9.2.1 pH Not determined

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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	1.200
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	Temperatures > 38°C, light, 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	Stable material if stored and used as directed. Polymerization will occur 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 Embrace resins may cause eye and respiratory irritation.

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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 <i>Effects and Side-Effects of Dental Restorative Materials</i> : "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	Eco-toxicity	Avoid release of uncured material into the environment. To the best of our knowledge, polymerized material is inert. No other information is available. Follow all government regulations.
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13.0 Disposal Considerations

13.1	Regulations	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 Regulations	Embrace products are Class IIA Medical Devices 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 acrylate 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	S24/25: Avoid contact with skin and eyes. S3/9/49: Keep only in the original container in a cool, well ventilated place.

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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	Embrace products are for use by dental professionals only.
16.3	Restrictions on use	Embrace products are to be sold to and used 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) 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).
