


EN - Safety Data SheetTrade Name: **PULPDENT KOOL-DAM**

1.0 Commercial Product Name and Supplier																		
1.1	Commercial product name / designation	Kool-Dam Heatless Liquid Dam & Block Out Resin																
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: 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 Limited Tower Business Centre, 2nd Floor, Tower Street, Swatar, BKR 4013 Malta																
	UK Responsible Person	Advena Limited Pure Offices, Plato Close Warwick, CV34 6WE United Kingdom																
	CH Authorized Representative	MedEnvoy Switzerland Gotthardstrasse 28, 6302 Zug, Switzerland																
2.0 Hazards Identification																		
2.1	Classification	Irritant.																
2.1.1	Classification according to Regulation (EC) No 1272/2008 [CLP]	<table><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																
2.2	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+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing.																	
	P337+P317: If eye irritation persists, get medical help.																	
	P302+P352: If on skin, wash with plenty of soap and water.																	

EN - Safety Data SheetTrade Name: **PULPDENT KOOL-DAM**

P333+P317: If irritation or rash occurs, get medical help.

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

3.0 Composition				
3.1	Chemical characterization of the preparation		Aliphatic and Polyurethane Dimethacrylate Oligomer / Monomer in a light-cured, glass-filled paste.	
3.2	Hazardous ingredients			
	CAS Number	Name of the Ingredient	Concentration	Classification per Regulation (EC) No.1272/2008 (CLP)
	Proprietary	Aliphatic and Polyurethane Dimethacrylate Oligomer / Monomer	55-65%	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317
	112945-52-5	Amorphous silica	5 %	Eye irritation, 2, H319 STOT SE 3, H335 Skin irritation, 2, H315
4.0 First Aid Measures				
4.1	General Information		Minimal health hazard under normal conditions of use. May be irritating to eyes, respiratory system and skin on contact. Prolonged or repeated contact with Oligomer / Monomer 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 / 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.	

EN - Safety Data SheetTrade Name: **PULPDENT KOOL-DAM**

- | | | |
|-----|--|---|
| 5.4 | Special protective equipment for fire-fighters | A self-contained breathing apparatus should be worn by fire fighting personnel. |
|-----|--|---|

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.
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. Follow good hygiene practices. Remove applicator tip from syringe and recap immediately after use. Keep light-cured materials shaded from intense light sources.
7.2	Storage	Store tightly capped in original container at cool room temperature (<25°C). Avoid direct light, sources of ignition, extremes of temperature (>27°C/80°F, <5°C/40°F). 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	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 and 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	Follow all government regulations. Cure material before disposing.
9.0 Physical and Chemical Properties		
9.1	Characteristics	
9.1.1	Appearance /Color / Physical state	Light blue gel
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

EN - Safety Data SheetTrade Name: **PULPDENT KOOL-DAM**

9.2.6	Oxidizing properties	Not determined
9.2.7	Vapor pressure	< 1 mm Hg / 133 Pa / Id: B
9.2.8	Specific gravity	1.290
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 extremes (>80°F / 27°C, <40°F / 5°C), intense light, contamination.
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 build- up, release of carbon monoxide, carbon dioxide, oxides of nitrogen.
10.4	Further information	Polymerization will occur when 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
11.7	Clinical experience	Kool-Dam has been used safely and effectively in the US and internationally for about 10 years with 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. Follow all government regulations.
13.0	Disposal Considerations	
13.1	Regulations	Follow all local and national government regulations in disposing material or contaminated packaging.
14.0	Transport Information	
14.1	Restrictions	None. Not regulated by IATA.

EN - Safety Data SheetTrade Name: **PULPDENT KOOL-DAM**

15.0 Regulatory Information		
15.1	EU	Class I medical devices under the Medical Devices Regulation (EU) 2017/745
15.2	US FDA	Class I medical device
15.3	Health Canada	Class III medical device
16.0 Other information		
16.1	Hazard Statements	<p>H319: Eye irritation. Hazard category 2.</p> <p>H335: Specific Target Organ Toxicity - Single exposure; hazard category. 3. Respiratory tract irritation.</p> <p>H315: Skin irritation. Hazard category 2.</p> <p>H317: Skin Sensitization. Hazard category 1.</p>
16.2	Precautionary Statements	<p>P261: Avoid breathing vapor.</p> <p>P280: Wear protective gloves and eye protection</p> <p>P305 + P351+P338: If in eyes, rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing.</p> <p>P337 + P317: If eye irritation persists, get medical help.</p> <p>P302 + P352: If on skin, wash with plenty of soap and water.</p> <p>P333 + P317: If irritation or rash occurs, get medical help.</p> <p>P410 + P411: Protect from sunlight. Store at temperature not exceeding 27°C / 80°F.</p>
16.3	Restrictions on use	Pulpdent 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	<p>National Institute for Occupational Safety (NIOSH)</p> <p>US Occupational Safety and Health Administration (OSHA)</p> <p>Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP), Regulation (EU) No 487/2013 and Regulation (EC) No. 1907/2006 (REACH).</p> <p>European Chemicals Agency Guidance on the compilation of safety data sheets Version 4.0 April 2020</p>
16.6	Information which has been added, deleted or revised.	This Safety Data Sheet has been revised to meet the requirements of the GHS SDS format, Regulations (EC) No. 487/2013 (CLP), , (EC) No. 1907/2006 (REACH) and ECHA Version 4.0 April 2020.