


Safety Data SheetTrade Name: **PULPDENT FLOWS-RITE™**

1.0 Commercial Product Name and Supplier																		
1.1	Commercial product name / designation	Flows-Rite™ Multi-Purpose Flowable Composite & 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	Telephone: 1 617 926-6666 / Fax: 1 617 926-6262																
	Pulpdent Corporation	Email: Pulpdent@pulpdent.com																
	80 Oakland Street, P.O. Box 780																	
	Watertown, MA 02472 USA																	
1.4	Emergency Number	24 Hour Emergency: 1-800-535-5053 (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]	<table><thead><tr><th>Hazard Class</th><th>Hazard Category</th><th>Hazard Statement</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>	Hazard Class	Hazard Category	Hazard Statement	Eye irritation	2	H319	STOT SE	3	H335	Skin irritation	2	H315	Skin sensitization	1	H317	
Hazard Class	Hazard Category	Hazard Statement																
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.																	
	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 FLOWS-RITE™**

3.0	Composition				
3.1	Chemical characterization of the preparation		Glass filler materials in methacrylate resins.		
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 methacrylate ester monomers	55-65%	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	Amorphous silica	5 %	Xi (Irritant), R36/37/38	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. Do not inhale vapors. May cause sensitization by skin contact. Show this safety data sheet to medical personnel. Seek medical attention in case of uncertainty.		
4.2	Inhalation		Move to fresh air. If necessary, administer oxygen, artificial respiration and seek medical attention.		
4.3	Skin Contact		Take off contaminated clothing. Wash skin thoroughly with soap and running water for 15 minutes.		
4.4	Eye Contact		Keep eyelids apart and flush with running water for 15+ minutes. Seek medical attention.		
4.5	Ingestion		Rinse mouth with water. Do not induce vomiting. Seek immediate medical attention. May be irritating to mucous membranes.		
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, especially in amounts greater than in this product.		
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 uncured, spilled material. Cured/set-up material is, to our knowledge, inert. Follow all government regulations.		

Safety Data SheetTrade Name: **PULPDENT FLOWS-RITE™**

6.3 Method for clean up 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. Remove applicator tip from syringe; cap container immediately after use. Keep light cure materials shaded from intense light sources.

7.2 Storage Store product 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). 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 restorative 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 will control airborne vapors.

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

8.2.1.3 Eye protection Usual safety glasses

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

8.2.1.5 Other controls Nearby emergency eye wash fountain. 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 Tooth-colored 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 1.930

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 FLOWS-RITE™**

9.2.12 Vapor density Not determined

9.2.13 Evaporation rate Not determined

10.0 Stability and reactivity

10.1	Conditions to avoid	Avoid temperature extremes (>80°F / 27°C, <40°F/ 5°C/), intense light, moisture, 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 and release of carbon monoxide, carbon dioxide, and oxides of nitrogen.
10.4	Further information	Stable 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 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	Flows-Rite has been used safely and effectively for more than 15 years without any 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. 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	Class IIa medical device under MDD 93/42/EEC.
15.2	US FDA	Class II medical device

Safety Data SheetTrade Name: **PULPDENT FLOWS-RITE™**

15.3 Health Canada

Class III medical device

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. 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 to be 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 the 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.