

SAFETY DATA SHEETS

This SDS packet was issued with item:

075899570

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).

075899455 075899463 075899471 075899489 075899497 075899505 075899513 075899521 075899539 075899547

MATERIAL SAFETY DATA SHEET: FLOWS-RITE™IDENTITY

Trade Name: FLOWS-RITE
 Chemical Description: Glass filler materials in methacrylate resins.
 Product Use: Flowable dental composite

SECTION I

Pulpdent Corporation
 80 Oakland Street
 Watertown, MA 02472 USA

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

Date prepared: September 1, 2008

SECTION II - HAZARDOUS INGREDIENTS

	CAS Number	PEL /TLV
Uncured methacrylate resin mixture	-----	Not established
Amorphous silica	112945-52-5	6 mg/m ³ / 10 mg/m ³
Sodium fluoride	7981-49-4	2.5 mg/m ³ (as F)

DOT HAZARD CLASSIFICATION: Not regulated
 WHMIS CLASSIFICATION: D-2 possible irritant
 NFPA HMIS RATING: HEALTH: 1 FLAMMABILITY: 0 REACTIVITY: 1

SECTION III - PHYSICAL / CHEMICAL CHARACTERISTICS

Specific Gravity: 1.930 Vapor Pressure: <1 mm Hg Vapor Density: 1
 Solubility in water: Nil Odor Threshold: Not established
 Appearance and Odor: Thin paste with faint characteristic odor in universal and tooth shades.

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 are recommended. Water spray may be used to keep fire exposed containers cool.
 Special Fire Fighting Procedures: A self-contained breathing apparatus should be worn by fire fighting personnel. 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 >100°F, intense 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 >100°F, intense light.

SECTION VI - HEALTH HAZARD DATA

Summary of Acute Hazards: Minimal health hazard under normal conditions of dental practice. May be irritating to eyes, mucous membranes or skin on contact.

<i>Route of Exposure</i>	<i>Signs & Symptoms</i>
Inhalation	May be irritating to mucous membranes
Eye Contact	May be irritating
Skin Absorption	Not applicable
Skin Contact	Primary route of exposure. May be irritating
Ingestion	May be irritating to mucous membranes.

Summary of Chronic Hazards: Methacrylate resins may be sensitizing in certain susceptible individuals.

Carcinogenicity	None known
Teratogenicity	None known.
Mutagenicity	None known.
Reproductive Toxicity	None known.

Emergency First Aid Procedures:

Inhalation	Move to fresh air. Administer oxygen or artificial respiration as necessary and seek medical attention for difficult breathing.
Eye contact	Flush eyes under running water for 15+ minutes. Seek medical attention for continued irritation or redness.
Ingestion	Consult physician immediately.
Skin contact	Wash skin with soap and water for 15+ minutes.

SECTION VII - PRECAUTIONS FOR SAFE HANDLING & USE

Handling and Storage Precautions: Keep tightly capped in original container. Avoid temperature extremes, intense light, moisture and contamination.

Release or Spill: Absorb and/or wipe up spill with suitable material (paper towels, cloths); collect for disposal. Wash area of spill with alcohol.

Waste Disposal Method: Follow all government regulations.

Other Precautions: Re-cap syringe immediately after use to prevent polymerization.

SECTION VIII - CONTROL MEASURES

Respiratory Protection: None required.

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

Protective Gloves: Recommended.


Eye Protection: Safety glasses are recommended.

Other Protective Clothing or Equipment: Lab coat should be worn to protect skin; 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 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	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 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 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	
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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															
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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.

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.

15.0 Regulatory Information

15.1 EU Class IIa medical device under MDD 93/42/EEC.

15.2 US FDA Class II medical device

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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.