

Safety Data SheetTrade Name: **SEAL-RITE™ PIT AND FISSURE SEALANT**

1.0 Commercial Product Name and Supplier				
1.1	Commercial product name / designation	Seal-Rite Pit and Fissure Sealant Seal-Rite Low Viscosity Pit and Fissure Sealant		
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 Telephone Number	1-800-535-5053 (24 Hour / 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]	<u>Hazard Class</u> Eye irritation STOT SE Skin irritation Skin sensitization	<u>Hazard Category</u> 2 3 2 1	<u>Hazard Statement</u> H319 H335 H315 H317
2.1.2	Classification according to Directive 67/548/EEC	Irritant; Xi; R 36/37/38 – 43 (See SECTION 16 for full text of risk phrases)		
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.			

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3.0	Composition				
3.1	Chemical characterization of the preparation:		Methacrylate ester monomers in a light-cured, glass-filled paste.		
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. Prolonged or repeated contact with methacrylate 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.		
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.		

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6.3 Method for clean up Absorb/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 trained in its use. Follow good hygiene practices. Remove applicator tip from syringe and cap container immediately after use. Keep light-cured 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 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; wearing a lab coat.

8.2.1.5 Other controls Emergency eye wash fountain. 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 Appearance / Color .

9.1.1 Color / Physical state Off-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 Seal-Rite: 1.550; Seal-Rite LV: 1.290

9.2.9 Solubility in water Nil

9.2.10 Partition coefficient Not determined

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9.2.11	Viscosity	Not determined
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), 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 and release of carbon monoxide, carbon dioxide, oxides of nitrogen.
10.4	Further information	Direct light will polymerize light-cured material.

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 this 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	Seal-Rite and Seal-Rite-LV have been used safely and effectively by dentists in the US and internationally for more than 15 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.
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13.0 Disposal Considerations

13.1	Regulations	Polymerize before disposal. 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 by IATA.
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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

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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	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 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.