

Patterson® Pit & Fissure Sealant Visible Light Cure - Fluoride Releasing

Regular Viscosity - 34.4% Filled

Radiopaque

Low Viscosity - 7.7% Filled

Store in cool dry place

Off-white shade

Avoid contact with eyes

Instructions for Use

- Clean enamel surfaces thoroughly with oil-free cleaning paste.
- Rinse well removing all residual paste from pits and fissures.
- Isolate the area to be sealed with cotton rolls. Prevent saliva contamination. Dry area thoroughly with clean, uncontaminated, oil-free and moisture-free compressed air.
- Apply Patterson® etch gel, or your preferred 35-40% enamel etching gel to the prepared enamel surface for 20 seconds. Rinse well. Do not disturb this surface.
- Replace wet cotton rolls with dry ones, but do not contaminate the treatment site with saliva.
- Dry the etched surface with clean, uncontaminated compressed air. Avoid blowing saliva onto tooth surfaces. If enamel does not appear chalky white, etch and dry surfaces again.
- It is important to avoid contamination at this time. Do not disturb the etch surfaces. If contamination occurs, wash and dry surface and etch again. Wash and dry again and proceed.
- Place 22 gauge applicator on syringe and carefully start flow of sealant. Never force the syringe plunger. Use a new applicator tip for each patient.
- Generously apply to pit and fissures, flowing sealant from cusp to cusp, but do not cover the marginal ridges.
- Light cure for at least 30 seconds, depending on the light you are using.
- Inspect the sealant surfaces. If coverage is incomplete, apply more sealant. If tooth has been contaminated, etch again for 10 seconds, wash, dry and then place additional sealant.
- Check and adjust occlusion, as required.

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 / ld: B
9.2.8	Specific gravity	Regular Viscosity: 1.550; Low Viscosity: 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	> 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	Under fire conditions and with amounts far greater than that supplied in this product, hazardous products 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	Pit and Fissure Sealants 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.
13.0 Disposal Considerations		
13.1	Regulations	Polymerize before disposal. 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 devices under MDD 93/42/EEC.
15.2	US FDA	Class II medical devices
15.3	Health Canada	Class III medical devices

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 27oC / 80oF.
16.4	Restrictions on use	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.

Manufactured for:

Fabriqu  pour :

Patterson Dental Supply, Inc.
1031 Mendota Heights Road
Saint Paul, MN 55120
P131320C (4/16)

Patterson® Scellant pour puits et fissures

Photopolymérisation visible - Libération de fluorure

Viscosité régulière - charge de 34,4%

Radio-opaque

Faible viscosité - charge de 7,7%

Entreposer dans un endroit frais et sec

Teinte blanc cassé


Éviter tout contact avec les yeux

Mode d'emploi

- Nettoyez à fond les surfaces en émail avec une pâte de nettoyage sans huile.
- Bien rincer et retirez tous les résidus de pâte des puits et des fissures.
- Isolez la partie traitée avec des rouleaux de coton. Évitez toute contamination par la salive. Bien assécher au moyen d'un jet d'air non contaminé et libre de toute humidité et d'huile.
- Appliquez le gel de mordantage de marquee Patterson®, ou votre gel de mordantage pour l'émail préféré (35-40%) sur la surface préparée de l'émail durant 20 secondes. Rincez à fond. Ne touchez pas cette surface.
- Remplacez les rouleaux de coton mouillés par des secs, mais assurez-vous de ne pas contaminer la surface traitée avec de la salive.
- Asséchez la surface mordancée au moyen d'un jet d'air non contaminé. Évitez de soufler de la salive sur les surfaces de la dent. Si l'émail ne semble pas être d'une couleur blanc craie, mordancez et asséchez de nouveau.
- Il est essentiel, à ce stade-ci, d'éviter toute contamination. Ne touchez pas aux surfaces mordancées. En cas de contamination, lavez et asséchez de nouveau et poursuivez.
- Insérez un applicateur de calibre 22 sur las seringue et amorcez soigneusement le flot de scellant. Ne forcez jamais le piston de la seringue. Utilisez un nouvel applicateur pour chaque patient.
- Appliquez généreusement le scellant dans les cavités et les fissures, de cuspide en cuspide, sans toutefois excéder la limite des rebords.
- Photopolymérisez durant au moins 30 secondes, selon la force de la lumi-ère que vous utilisez.
- Vérifiez les surfaces traitées. Si le remplissage n'est pas adéquat, appliquez plus de scellant. Si la dent a été contaminée, mordancez une autre fois durant 10 secondes, lavez, séchez et appliquez une nouvelle couche de scellant.
- Vérifiez et ajustez l'occlusion au fur et à mesure.

Trade Name: Patterson PIT AND FISSURE SEALANT

1.0 Commercial Product Name and Supplier		
1.1	Commercial product name/ designation	Patterson 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	Patterson Companies, Inc. 1031 Mendota Heights Rd., St. Paul, MN 55120 Telephone: 800.328.5536 Fax: 651.686.9331

2.0 Hazards Identification			
2.1	Classification	Irritant.	
2.1.1	Classification according to Regulation (EC) No 1272/2008 [CLP]	Hazard Class	Hazard Category
		Eye irritation	2
		STOT SE	3
		Skin irritation	2
		Skin sensitization	1
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.	

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.1278/2008 (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		
Self-contained breathing apparatus.		
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/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.