

IMPRESIL™

Heatless Liquid Dam and Block-Out resin
Lichthärtend

PRODUKTBESCHREIBUNG

IMPRESIL™ wurde speziell entwickelt, um Zähne und Zahnfleisch vor Irritationen zu schützen.
• Keine Erwärmung beim Lichthärten. Geringe exotherme Reaktion verhindert Brennen und Schmerzen und ist angenehm für den Patienten.
• IMPRESIL™ ist geförmig und tropft nicht. Einfach auftragen und nur einmal lichthärten. Erspart mehrere Arbeitsgänge und wiederholtes Lichthärten.
• Bleibt nach dem Aushärten flexibel. Ein Kofferdam Ersatz - das gummiartig ausgehärtete Material ist leicht zu entfernen und ist reißfest.

INDIKATIONEN

• Power-Bleaching: IMPRESIL™ wird verwendet, um das Zahnfleisch während des Bleichvorgangs zu schützen.
• Ausblockmasse: IMPRESIL™ wird verwendet, um Unterschnitte auszublocken und gingivale Unterscheidungen vor der Abdrucknahme von Kronen und Brücken auszukleiden.
• Sandstrahlen: IMPRESIL™ wird verwendet, um die Gingiva abzudecken und beim Sandstrahlen zu schützen. Er kann auch zum Abdecken der Zähne angewendet werden.

VERARBEITUNGSANLEITUNG

1. Eine grüne 18-Gauge oder rosa 20-Gaugen Applikatorspitze auf die Luer-Lock-Spritze aufschrauben.
2. Eine 1–2 mm dicke Schicht IMPRESIL™ auf die zu schützende Gingiva oder Zahnoberflächen vor dem Bleichen oder Sandstrahlen auftragen. Sandstrahlen und andere Verfahren erfordern intraoralen Schutz. Ebenso kann es vor der Abformung verwendet werden um Unterschnitte auszublocken. IMPRESIL™ ist so ausgelegt, dass dieser vor der Härtung auch über mehrere Zähne aufgetragen werden kann, ohne wegzufließen. Nach Gebrauch Spritze sofort wieder verschließen.
3. Lichthärtung für ca. 10 Sekunden, je nach Lichthärtegerät.

Anmerkung: Mehrfachdosis-Spritzen sollten entweder in einer frischen Schutzhülle für jeden Patienten verpackt oder nach jedem Patienten angemessen gereinigt und desinfiziert werden.

Nur für den zahnärztlichen Gebrauch.

IMPRESIL™

Diga liquida, atermica, per isolamento della gengiva e sottosquadri
Fotopolimerizzabile

DESCRIZIONE DEL PRODOTTO

IMPRESIL™ è stata formulata unicamente per eliminare i problemi associati all'utilizzo delle comuni dighe liquide.
• Non surriscalda durante la polimerizzazione. La bassa reazione esotermica elimina il bruciore ed il dolore assicurando un elevato comfort al paziente.
• Non cola. Il prodotto è applicato e polimerizzato con un'unica operazione. Sono così eliminati i passaggi multipli di applicazione e di polimerizzazione.
• Rimane flessibile dopo la polimerizzazione. Sostituisce interamente la diga di gomma. Il materiale non diventa rigido dopo la polimerizzazione e viene rimosso facilmente in un unico pezzo senza lacerarsi.

INDICAZIONI

• Power Bleaching: IMPRESIL™ protegge i tessuti soffici durante i trattamenti di sbiancamento alla poltrona ed i denti adiacenti alle aree sottoposte ad abrasione con sabbiatrici intraorali.
• Protesi: IMPRESIL™ può essere usato per eliminare sottosquadri e difetti gengivali prima di prendere impronte per corone e ponti.
• Sabbiatrice: IMPRESIL™ è usato per mascherare e proteggere la gengiva durante la sabbatura. È anche posto sulle aree di denti da mascherare durante il processo di sabbatura.

ISTRUZIONI PER L'USO

1. Fissare l'applicatore verde da 18-gauge oppure rosa da 20-gauge sulla siringa "luer lock".
2. Applicare uno strato di 1-2 mm circa sulle superfici da proteggere prima delle operazioni di sbiancamento, sabbatura, mordenzatura e altre procedure che richiedano una protezione intraorale, o nei sottosquadri da eliminare prima della presa dell'impronta. IMPRESIL™ non cola permettendo l'applicazione simultanea su più denti prima della polimerizzazione. Richiudere immediatamente dopo l'uso.
3. Fotopolimerizzare per 10 secondi, tempo che può variare leggermente in funzione del tipo di lampada utilizzata.

Nota: Le siringhe multidose devono essere rivestite da una copertura monouso prima dell'utilizzo su ogni paziente o pulite e disinfettate tra un paziente e l'altro.

Esclusivamente per uso odontoiatrico.

La Maison Dentaire SA

REV. 5 : March 3, 2022

SAFETY DATA SHEET

According to Regulation (EC) No. 1907/2006 (REACH) and Regulation (EC) No. 1272/2008 (CLP) Trade Name: IMPRESIL™

1.0 Commercial Product Name and Supplier			
1.1	Commercial product name / designation	Impresil 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	LA MAISON DENTAIRE SA Alte Churerstrasse 36 FL-9496 BALZERS LIECHTENSTEIN	
1.4	CH-REP / Importer	MEDIREL SA CH-6982 Agno Switzerland Tel. +41 91 604 54 34 info@medirel.ch	
1.4.1	Emergency Telephone Number	+41 91 604 54 34	
2.0 Hazards Identification			
2.1	Classification	Irritant	
2.1.1	Classification according to Regulation (EC) No 1272/2008 (CLP)	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.

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
		112945-52-5	Amorphous silica	5 %
			Proprietary	Aliphatic and Polyurethane Dimethacrylate Oligomer / Monomer
				Xi (Irritant) R36/37/38, R43
				Eye irritation, 2, H319, STOT SE 3, H335 Skin irritation, 2, H315 Skin sensitization, 1, H317
				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	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.
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. 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	Follow all government regulations. Cure material before disposing.

9.0 Physical and Chemical Properties		
9.1	Appearance / Color	
9.1.1	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

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, and 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	Impresil has been used safely on the domestic and international market for more than 10 years. During that time there have been no reports of adverse events.
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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.
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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 Regulations	Class I Medical Devices under MDD 93/42/EEC.
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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	La Maison Dentaire SA 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 La Maison Dentaire SA bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate.
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16.6	Sources of key data	National Institute for Occupational Safety (NIOSH) 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
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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, Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH). Specifically Sections 2.1, 2.2, 3.2, 16.2, 16.3 have been modified.
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REV: 03/2022

IMPRESIL™
Heatless Liquid Dam and Block Out Resin
Light Cure



shelf-life is indicated on outer package

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2140322

IMPRESIL™
Heatless Liquid Dam and Block Out Resin
Light Cure
KIT: 3 x 3 mL syringes IMPRESIL

PRODUCT DESCRIPTION
IMPRESIL™ has been uniquely formulated to eliminate the problems associated with paint on dam materials.

- Does not produce heat when cured. Low exothermic reaction eliminates burning and pain assuring patient comfort.
- Does not run. A single application is light cured one time only. Eliminates multiple passes and multiple light curing procedures.
- Remains flexible after curing. Truly a rubber dam substitute, the rubbery cured material is easily removed and is tear resistant.

INDICATIONS

- Power bleaching: IMPRESIL™ is used to protect the gingival during power bleaching procedures.
- Block-out resin IMPRESIL™ is used to block out undercut and gingival embrasures prior to taking impressions for crowns and bridges.
- Sandblasting: IMPRESIL™ is used to mask and protect the gingiva during sandblasting. It is also placed on the areas of teeth to be masked during the sandblasting process.

DIRECTIONS FOR USE

- Place a green 18-gauge or pink 20-gauge applicator tip securely on the luer lock syringe.
- Apply a coat of IMPRESIL™ 1-2 mm thick on the gingival or tooth surfaces to be protected prior to power bleaching, sandblasting or other procedures requiring intraoral protection, or place in areas to be blocked out prior to taking impressions. IMPRESIL™ does not run and is designed so that it can be placed over multiple teeth before curing. Re-cap immediately after use.
- Light cure for 10 seconds, depending on the light you are using.

Note: Apply disposable barrier sleeves/wraps over multiple-use dental dispensers before use with each patient. For additional information, refer to: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/ucm404472.htm>

Restricted to use by dental professionals only.

IMPRESIL™
Digue liquide, athermique, pour isolation de la gencive et Block-Out résine
Photopolymérisable

DESCRIPTION DU PRODUIT
IMPRESIL™ a été formulé de manière unique pour éliminer les problèmes associés aux digues liquides :

- Ne produit de chaleur lors de la photopolymérisation. Une réaction exothermique faible élimine les sensations de brûlures et douleurs assurant le confort du patient.
- Ne coule pas. Une seule application suffit. Pas de besoin de passages multiples et / ou de procédures multiples de photo-polymérisation.
- Reste flexible après séchage. Un réel substitut de digue, le matériau durci est caoutchouteux et se retire facilement. Résiste aux déchirures.

INDICATIONS

- Power Bleaching : IMPRESIL™ est utilisé pour protéger la gencive pendant les procédures de blanchiment.
- Block-Out résine : IMPRESIL™ est utilisé dans les contre-dépouilles et embrasures gingivales avant la prise d'empreintes pour couronnes et ponts.
- Sablage : IMPRESIL™ est utilisé pour masquer et protéger la gencive pendant le sablage / ponçage. Il est également placé sur les zones de sablage.

MODE D'EMPLOI

- Placer un embout-applicateur vert à 18-gauge ou rose à 20-gauge sur la seringue «luer lock».
- Appliquer une couche de IMPRESIL™ de 1 à 2 mm d'épaisseur sur la gencive, dents et/ou surfaces à protéger avant au le blanchiment, le sablage ou autres procédures nécessitant une protection. IMPRESIL™ ne coule pas et est conçu de telle sorte qu'il peut être placé sur plusieurs dents avant le durcissement. Reboucher immédiatement après usage.
- Photopolymériser pendant 10 secondes, en fonction de la lumière que vous utilisez.

Remarque : seringues multidoses doivent être enfermées dans une nouvelle barrière protectrice pour chaque patient et nettoyées et désinfectées entre les patients, le cas échéant.

Exclusivement pour usage professionnel dentaire.