

## 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	<i>Impresil Healess Liquid Dam &amp; Block Out Resin</i>
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	MEDIREL SA CH-6982 Agno Switzerland Tel. +41 91 604 54 34 info@medirel.ch

2.0 Hazards Identification			
2.1	Classification	Irritant.	
2.1.1	Classification according to Regulation (EC) No 1272/2008 [CLP]	<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
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.**

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### 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 Oligo / Monomer in a light-cured, glass-filled paste.

3.2 Hazardous ingredients

CAS Number	Name of the Ingredient	Concentration	Classification according to 67/548/EEC	Classification according to Regulation (EC) No.1272/2008 (CLP)
Proprietary	Aliphatic and Polyurethane Dimethacrylate Oligo / Monomer	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      Minimal health hazard under normal conditions of use. May be irritating to eyes, respiratory system and skin on contact. Prolonged or repeated contact with Oligo/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.

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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 cap container immediately after use. Keep light-cured materials shaded from intense light sources.
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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 of this product in the quantity provided.

8.2.1.1 Respiratory protection None required. Good general ventilation is sufficient to control any airborne vapors from uncured material.

8.2.1.2 Hand protection No special requirements. The usual surgical gloves worn by dental staff will limit contact with uncured material.

8.2.1.3 Eye protection No special requirements other than the usual safety glasses worn by dental staff.

8.2.1.4 Skin protection No special requirements. Good personal hygiene and safety practices and wearing a lab coat should protect dental staff from unnecessary exposure to uncured material.

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 Characteristics

9.1.1 Appearance / 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

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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 and release of carbon monoxide, carbon dioxide, and oxides of nitrogen.
10.4	Further information	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.

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11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known
11.6	Empirical data	Not available
11.7	Clinical experience	Impresil has been used safely and effectively in the US and internationally for about 10 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. 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 by IATA.
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### 15.0 Regulatory Information

15.1	<b>EU</b>	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

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exceeding 27°C / 80°F.

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|------|---|--|
| 16.4 | Restrictions on use                                   | Medirel 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 Medirel SA 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)<br>US Occupational Safety and Health Administration (OSHA)<br>Eur-Lex European Union Law: Regulation (EC) No. 1272/2008 (CLP) and Regulation (EC) No. 1907/2006 (REACH).<br>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, 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. 4, 10.07.2019 by the Technical & Regulatory Affairs Department**

**REV. 5, 03.03.2022 by the Technical & Regulatory Affairs Department**