

## Safety Data Sheet

According to EC Directive 2001/58, Directive 93/42, Amended by Directive 2007/47/CE and regulation UE 453/2010.  
Complies with regulation (EC) 1907/2006 and regulation 1272/2008.

Trade Name: **ROCANAL IRRIGATION**

<b>1.0 Commercial Product Name and Supplier</b>																													
1.1	Commercial Product Name and Supplier <b>ROCANAL IRRIGATION</b> , dental solution																												
1.2	Application / Use Dental material for use by dental professional only																												
1.2.2	SIC 851 Human health activity																												
1.3	Manufacturer, Importer																												
1.3.1	Manufacturer MEDREL SA. CH 6982 Agno Switzerland Telephone: +41 91 604 54 34 info@medirel.ch																												
1.3.2	EC-Rep LA MAISON DENTAIRE SA. Pralawisch, 13 FL-9496 BALZERS / LIECHTENSTEIN																												
<b>2.0 Hazards Identification</b>																													
2.1	Classification																												
2.2	Adverse human health effects None, if handled according to directives																												
<b>3.0 Composition/Information on components</b>																													
3.1	Chemical characterization of the preparation: <table border="1" style="width: 100%; border-collapse: collapse; margin-top: 5px;"> <thead> <tr> <th style="width: 60%;"></th> <th style="width: 10%;">g /%</th> <th style="width: 15%;">N° CE</th> <th style="width: 15%;">CAS n°</th> </tr> </thead> <tbody> <tr> <td>Benzethonium chloride</td> <td style="text-align: center;">0,2</td> <td style="text-align: center;">204-479-9</td> <td style="text-align: center;">121-54-0</td> </tr> <tr> <td>Fenoxyethanol</td> <td style="text-align: center;">2</td> <td style="text-align: center;">204-589-7</td> <td style="text-align: center;">122-99-6</td> </tr> <tr> <td>EDTA</td> <td style="text-align: center;">0,2</td> <td style="text-align: center;">200-449-4</td> <td style="text-align: center;">60-00-4</td> </tr> <tr> <td>Methylene blue</td> <td style="text-align: center;">4,5</td> <td style="text-align: center;">200-515-2</td> <td style="text-align: center;">61-73-4</td> </tr> <tr> <td>IsopropylicAlcool</td> <td style="text-align: center;">0,00025</td> <td style="text-align: center;">200-578-6</td> <td style="text-align: center;">67-63-0</td> </tr> <tr> <td>Purified water</td> <td style="text-align: center;">87,6</td> <td style="text-align: center;">/</td> <td style="text-align: center;">/</td> </tr> </tbody> </table>		g /%	N° CE	CAS n°	Benzethonium chloride	0,2	204-479-9	121-54-0	Fenoxyethanol	2	204-589-7	122-99-6	EDTA	0,2	200-449-4	60-00-4	Methylene blue	4,5	200-515-2	61-73-4	IsopropylicAlcool	0,00025	200-578-6	67-63-0	Purified water	87,6	/	/
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3.2	Hazardous ingredients NONE																												
<b>4.0 First Aid Measures</b>																													
4.1	General Information:																												
4.2	Inhalation Not applicable																												
4.3	Skin Contact Wash skin thoroughly with soap and water.																												
4.4	Eye Contact Flush with running water. Get medical attention																												

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4.5	Ingestion	Get medical attention. Never give anything by mouth to an unconscious person.
4.6	Precautions for first responders	Not applicable.
4.7	Information for physicians Symptoms	Irritation or redness in eyes, throat or on skin.
	Hazards	None
	Treatment	As above under First Aid.

### 5.0 Fire Fighting Measures

5.1	Suitable extinguishing media:	Powder, foam, carbon dioxide, water spray
5.2	Extinguishing media to avoid	None
5.3	Special exposure hazards in a fire	N/A
5.4	Special protective equipment for fire-fighters	A self-contained breathing apparatus should be worn by fire fighting personnel. Cool exposed containers with water spray.

### 6.0 Accidental Release Measures

6.1	Personal precautions.	Wear safety glasses, gloves and lab coat. Use only in well-ventilated areas.
6.2	Environmental precautions	Do not empty into drains
6.3	Method for clean up	Take up mechanically

### 7.0 Handling and Storage

7.1	Handling	For use only by dental professionals. Follow good hygiene practices. Do not smoke, eat or drink while using. Avoid direct / strong light sources, extremes of temperature.
	Safe handling advice:	Wear suitable gloves
7.2	Storage	Store product at cool room temperature (+8°-+25°C) and in a dry, well ventilated area. Avoid direct, strong light, sources of ignition and extremes of temperature. Shelf life for unopened product is 5 years from date of manufacture, provided that the material has been stored properly.
	Recommended packaging	Glassware
7.3	Specific uses	Dental material

### 8.0 Exposure Controls / Personal Protection

8.1	Exposure limit values	PEL: Not established. TLV: Not established.
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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	Do not breathe vapors. Good general ventilation is sufficient to control any airborne vapors.
8.2.1.2	Hand protection	No special requirements. The usual surgical gloves worn by dental staff will be sufficient.
8.2.1.3	Eye protection	No special requirements other than the <b>usual safety glasses</b> 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 material.
8.2.1.5	Hygiene measures	Do not drink or eat when using.
8.2.2	Environmental exposure controls	Do not discharge into drains or into the environment.

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### **9.0 Physical and Chemical Properties**

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9.1	Appearance / Color	
9.1.1	Color / Physical state	Slightly blue liquid
9.1.2	Odor	Slightly alcoholic
9.2	Important health, safety and environmental information	
9.2.1	pH	Not determined
9.2.2	Melting point	Not applicable
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	Relative vapor density	Not applicable
9.2.8	Density	Ca. 1.0 g/cm <sup>3</sup>
9.2.9	Solubility in water	Very soluble
9.2.10	Partition coefficient	Not determined
9.2.11	Viscosity	Not determined

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9.2.12 Vapor density Not determined

9.2.13 Evaporation rate Not determined

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### 10.0 Stability and reactivity

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10.1 Conditions to avoid Heat and sunlight

10.2 Materials to avoid

10.3 Hazardous decomposition products Unknown; when heated to decomposition or in case of fire, irritating and toxic fumes may be emitted.

10.4 Further information Stable material if stored and used as directed.

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### 11.0 Toxicological information

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11.1 Acute oral toxicity I.N. LD 50 : 5000mg/kg (rat)

11.2 Irritation and corrosiveness  
Of skin: not available  
Of eyes: not available  
Specific effects: None

11.3 Sensitization

11.4 Sub-acute, sub-chronic and prolonged toxicity None

11.5 Carcinogenicity, Mutagenicity, Reproductive Toxicity None known

11.6 Empirical data Not available

11.7 Clinical experience General usage of the component materials for more than 20 years indicates a high benefit-to-risk ratio There is no evidence of short-term or long-term risk or suspicion of any problems.

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### 12.0 Ecological Information

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12.1 Eco-toxicity Avoid release material into drains or into the environment. Follow all government regulations.

12.2 Persistence and degradability Not available

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### 13.0 Disposal Considerations

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13.1 Waste from residues Use proper disposal or incineration following all local and national government regulations in disposing material or contaminated packaging.

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<b>14.0 Transport Information</b>		
<b>Restrictions</b>	This product does not require transportation classification.	
<b>15.0 Regulatory Information</b>		
15.1	EU Regulations This product requires classification according to the criteria established by the EEC.	Medical device Class I in compliance with Directive (EC) 93/42, as amended by Directive 2007/47/EC, 2001/58/EC, Regulation (EU) 453/2010 and Regulation (EC) No 1907/2006 and Regulation 1272/2008
15.2	Information on the warning label	none
15.2.1	Hazard symbol	none
15.2.2	Hazardous ingredient	none
15.2.3	Risk phrases	none
15.2.4	Safety phrases	S24/25: Avoid contact with skin and eyes. S3/49: Keep only in the original container in a cool place.
<b>16.0 Other information</b>		
16.1	List of relevant R phrases	R36/37/38: Irritating to eyes, respiratory system and skin. R43: Sensitizing by skin contact.
16.2	Training advice	For use by dental professionals only.
16.3	Restrictions on use	To be sold to and used by dental professionals only.
16.4	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/Medirel bears legal responsibility. The user should review any recommendations in the specific context of the intended use to determine whether they are appropriate.
16.5	Sources of key data	Eur-Lex European Union Law
16.6	Information which has been added, deleted or revised.	This Safety Data Sheet has been revised to meet the requirements of Regulation (EC) 93/42 as amended by 2007/47/CE and 2001/58/CE and regulation EU 453/2010. Complies with regulation (CE) 1907/2006 and regulation 1272/2008.

Created 03/05/2011

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Revision 3: May 2021 by the Quality Service & Regulatory Affaires