

## 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<br>MEDREL SA.<br>CH 6982 Agno<br>Switzerland<br>Telephone: +41 91 604 54 34<br>info@medirel.ch  |           |          |       |        |                       |     |           |          |               |   |           |          |      |     |           |         |                |     |           |         |                   |         |           |         |                |      |   |   |
| 1.3.2  | EC-Rep<br>LA MAISON DENTAIRE SA.<br>Alte Churerstrasse 36<br>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 | / | / |
|  | 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   | /         | /        |       |        |                       |     |           |          |               |   |           |          |      |     |           |         |                |     |           |         |                   |         |           |         |                |      |   |   |
| 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<br>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.<br>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

### 10.0 Stability and reactivity

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.

### 11.0 Toxicological information

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.

### 12.0 Ecological Information

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

12.2 Persistence and degradability Not available

### 13.0 Disposal Considerations

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</b> | <b>Transport Information</b>   |  |
|             | <b>Restrictions</b>  | This product does not require transportation classification.   |
| <b>15.0</b> | <b>Regulatory Information</b>  |  |
| 15.1        | EU Regulations<br>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.<br>S3/49: Keep only in the original container in a cool place.   |
| 16.0        | Other information  |  |
| 16.1        | List of relevant R phrases   | R36/37/38: Irritating to eyes, respiratory system and skin.<br>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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