

## 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 PERMANENT GANGRENE R 3**

<b>1.0 Identification of the substance/Preparation and of the Company/Undertaking</b>																																	
1.1	Identification of the substance or preparation <b>ROCANAL PERMANENT GANGRENE R 3</b>																																
1.2	Use of the substance/preparation Dental material for use by dental professional only. A permanent root canal filling cement to be used after complete preparation of a gangrenous canal.																																
1.2.2	SIC 851 Human health activity																																
1.3	Manufacturer MEDIREL SA. CH 6982 Agno Switzerland Tel. +41 91 604 54 34 Info@medirel.ch																																
1.3.2	EC-Rep LA MAISON DENTAIRE SA. Alte Churerstrasse 36 FL-9496 BALZERS / LIECHTENSTEIN																																
<b>2.0 Hazards Identification</b>																																	
2.1	Classification																																
2.2	Adverse human health effects Not classified as dangerous according to Directives EC																																
<b>3.0 Composition</b>																																	
3.1	Chemical characterization of the preparation: <b><u>Liquid: Alcoholic solution</u></b>																																
	<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">g/%</th> <th style="text-align: center;">N° CE</th> <th style="text-align: center;">CAS n°</th> </tr> </thead> <tbody> <tr> <td>Eugenol</td> <td style="text-align: center;">74</td> <td style="text-align: center;">202-589-1</td> <td style="text-align: center;">97-53-0</td> </tr> <tr> <td>Rosin</td> <td style="text-align: center;">8,950</td> <td style="text-align: center;">232-475-7</td> <td style="text-align: center;">8050-09-7</td> </tr> <tr> <td>Castor Oil</td> <td style="text-align: center;">5,000</td> <td style="text-align: center;">232-293-8</td> <td style="text-align: center;">8001-79-4</td> </tr> <tr> <td>Glycerin</td> <td style="text-align: center;">3,100</td> <td style="text-align: center;">200-289-5</td> <td style="text-align: center;">56-81-5</td> </tr> <tr> <td>Alcohol</td> <td style="text-align: center;">8,950</td> <td style="text-align: center;">200-578-6</td> <td style="text-align: center;">64-17-5</td> </tr> </tbody> </table>		g/%	N° CE	CAS n°	Eugenol	74	202-589-1	97-53-0	Rosin	8,950	232-475-7	8050-09-7	Castor Oil	5,000	232-293-8	8001-79-4	Glycerin	3,100	200-289-5	56-81-5	Alcohol	8,950	200-578-6	64-17-5								
	g/%	N° CE	CAS n°																														
Eugenol	74	202-589-1	97-53-0																														
Rosin	8,950	232-475-7	8050-09-7																														
Castor Oil	5,000	232-293-8	8001-79-4																														
Glycerin	3,100	200-289-5	56-81-5																														
Alcohol	8,950	200-578-6	64-17-5																														
	<b><u>Powder:</u></b> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th></th> <th style="text-align: center;">g/%</th> <th style="text-align: center;">N° CE</th> <th style="text-align: center;">CAS n°</th> </tr> </thead> <tbody> <tr> <td>Zinc oxide</td> <td style="text-align: center;">37,500</td> <td style="text-align: center;">215-222-5</td> <td style="text-align: center;">1314-13-2</td> </tr> <tr> <td>Titan dioxide</td> <td style="text-align: center;">13,800</td> <td style="text-align: center;">236-675-5</td> <td style="text-align: center;">13463-67-7</td> </tr> <tr> <td>Zinc stearate</td> <td style="text-align: center;">3,700</td> <td style="text-align: center;">/</td> <td style="text-align: center;">557-05-1</td> </tr> <tr> <td>Zinc acetate</td> <td style="text-align: center;">4,800</td> <td style="text-align: center;">209-170-2</td> <td style="text-align: center;">557-34-6</td> </tr> <tr> <td>Ortho phenyl phenol (OPP)</td> <td style="text-align: center;">5,500</td> <td style="text-align: center;">201-993-5</td> <td style="text-align: center;">90-43-7</td> </tr> <tr> <td>Calcium Wolframate</td> <td style="text-align: center;">34,200</td> <td style="text-align: center;">232-219-4</td> <td style="text-align: center;">7790-75-2</td> </tr> <tr> <td>Anis oil</td> <td style="text-align: center;">0,500</td> <td style="text-align: center;">/</td> <td style="text-align: center;">8007-70-3</td> </tr> </tbody> </table>		g/%	N° CE	CAS n°	Zinc oxide	37,500	215-222-5	1314-13-2	Titan dioxide	13,800	236-675-5	13463-67-7	Zinc stearate	3,700	/	557-05-1	Zinc acetate	4,800	209-170-2	557-34-6	Ortho phenyl phenol (OPP)	5,500	201-993-5	90-43-7	Calcium Wolframate	34,200	232-219-4	7790-75-2	Anis oil	0,500	/	8007-70-3
	g/%	N° CE	CAS n°																														
Zinc oxide	37,500	215-222-5	1314-13-2																														
Titan dioxide	13,800	236-675-5	13463-67-7																														
Zinc stearate	3,700	/	557-05-1																														
Zinc acetate	4,800	209-170-2	557-34-6																														
Ortho phenyl phenol (OPP)	5,500	201-993-5	90-43-7																														
Calcium Wolframate	34,200	232-219-4	7790-75-2																														
Anis oil	0,500	/	8007-70-3																														
3.2	Hazardous ingredients NONE																																

## 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 PERMANENT GANGRENE R 3**

<b>4.0 First Aid Measures</b>		
4.1	General Information	May be irritating to eyes, respiratory system and skin. Do not inhale vapors. Avoid contact with eyes and skin. May cause sensitization by skin contact. Show this safety data sheet to medical personnel. Get medical attention in case of uncertainty.
4.2	Inhalation	In case of prolonged exposure to the liquid, move to fresh air.
4.3	Skin Contact	Wash skin thoroughly with soap and water.
4.4	Eye Contact	Wash with running water. Get medical attention.
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	<b>Information for physicians</b>	
	Symptoms	Irritation or redness in eyes, throat or on skin.
	Hazards	None
	Treatment	As above under First Aid.
<b>5.0 Fire Fighting Measures</b>		
5.1	Suitable extinguishing media	Powder, sand, foam, carbon dioxide.
5.2	Extinguishing media to avoid	Do not use direct water stream
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.
<b>6.0 Accidental Release Measures</b>		
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.

### 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 PERMANENT GANGRENE R 3**

<b>7.0 Handling and Storage</b>		
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 4 years from date of manufacture, provided that the material has been stored properly.
	Recommended packaging:	Glassware
7.3	Specific uses	Dental material
<b>8.0 Exposure Controls / Personal Protection</b>		
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	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 usual <b>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.
<b>9.0 Physical and Chemical Properties</b>		
9.1	Appearance / Color	
9.1.1	Color / Physical state	<b>Powder:</b> white powder
9.1.2	Odor	Faint odor of anise oil
		<b>Liquid:</b> yellow to brown lightly viscous
		Characteristic odor of clove oil

### 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 PERMANENT GANGRENE R 3**

9.2	Important health, safety and environmental information	<b>Powder:</b>	<b>Liquid:</b>
9.2.1	pH	Not determined	Not determined
9.2.2	Boiling point	40-60°C	
9.2.3	Flash point	Not applicable	
9.2.4	Flammability (solid, gas)	Not applicable	
9.2.5	Explosive properties	Not applicable	Vapors can form explosive mix with air
9.2.6	Oxidizing properties	Not determined	
9.2.7	Vapor pressure	Not available	
9.2.8	Density	Ca. 1.0 g/cm <sup>3</sup>	
9.2.9	Solubility in water	Soluble	
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	
<b>10.0</b>	<b>Stability and reactivity</b>	<b>Powder:</b>	
10.1	Conditions to avoid	Heat, sunlight and moisture.	
10.2	Materials to avoid	Strong reducing and oxidizing agent.	
10.3	Hazardous decomposition products	Unknown; when heated to decomposition or in case of fire, irritating and toxic fumes may be emitted.	
10.4	Thermal decomposition:	Stable material if stored and used as directed.	
		<b>Liquid:</b>	
10.1.	Conditions to avoid	Heat and sunlight	
10.2	Materials to avoid	Oxidizing agents	
10.3.	Hazardous decomposition products	Unknown	
10.4.	Thermal decomposition	No decomposition if handled according to directives	
<b>11.0</b>	<b>Toxicological information</b>	<b>Powder:</b>	
11.1	Acute oral toxicity	I:N:LD 50: 5000 mg/kg (rat)	
11.2	Irritation and corrosivity	Skin: N/A Eyes: N/A Specific effects: none	
11.3	Sensitization	May be sensitizing. Prolonged or frequent skin contact may cause allergic skin reactions in sensitive individuals.	

**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 PERMANENT GANGRENE R 3**

11.4	Sub-acute, sub-chronic and prolonged toxicity	No data
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known
11.6	Empirical data	Not available
		<b>Liquid:</b>
11.1.	Acute oral toxicity	I:N: LD 50 : 5000mg / kg (rat)
11.2	Irritation and corrosivity of skin	Irritating on prolonged exposure
11.3	Irritation of eyes	Irritating on exposure
11.4	Specific effects	None
11.5	Carcinogenicity, Mutagenicity, Reproductive Toxicity	None known
11.6	Empirical data	Not available
11.7	Clinical experience	General usage of the 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 of material into the environment. No other information is available. 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.
------	---------------------	--

**14.0 Transport Information**

14.1	Restrictions	None. Not dangerous product referring to transport regulations.
------	--------------	---

**15.0 Regulatory Information**

15.1	This product requires classification according to the criteria of the EU Regulations	Registered as a Class IIA Medical Device under the Medical Devices Directive 93/42/EEC as amended by Directive 2007/47/CE and 2001/58/CE, Regulation (EU) 453/2010, Regulation (EC) 1907/2006 and Regulation 1272/2008.  <i>Notified Body</i> <b>KIWA CERMET ITALIA (CE 0475)</b> Via Cadriano 23 40057 Granarolo dell'Emilia (BO)
15.2	Information on the warning label	None

## 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 PERMANENT GANGRENE R 3**

15.2.1	Hazard symbol	None
15.2.2	Hazardous ingredient	None
15.2.3	Risk phrases	R36/37/38: Irritating to eyes, respiratory system and skin. R43: Sensitizing by skin contact.
15.2.4	Safety phrases	S24/25: Avoid contact with skin and eyes. S3/9/49: 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. 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 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 directive (UE) 453/2010. Complies with regulation (CE) 1907/2006 and regulation 1272/2008

Created on 03 May 2011

Revision 1: 09 August 2013 by the Service Quality & Regulatory Affairs

Revision 2: 24 September 2013 by the Service Quality & Regulatory Affairs

Revision 3: 12 January by the Service Quality & Regulatory Affairs

Revision 4: 01 October 2020 by the Service Quality & Regulatory Affairs

Revision 5: 10 November 2020 by the Service Quality & Regulatory Affairs

Revision 6: May 2021 by the Service Quality & Regulatory Affairs