

**Product: SEALITE LIQUIDE**

SDS No. 266267

Created on: 10/10/2008

Updated on: 08/10/2020

**1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING**

**1.1 PRODUCT identification**

**SEALITE LIQUIDE**

**1.2 Relevant use of mixture**

Liquid for sealing cement for root canals

**1.3 Information concerning safety data sheet supplier**

PRODUITS DENTAIRE PIERRE ROLLAND SAS

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**EMERGENCY CALL NUMBER**

**2. HAZARDS IDENTIFICATION**

**2.1 Classification of substance or mixture**

According to Regulation 1272/2008/EC



Skin Sens. 1 H317 May cause an allergic skin reaction.

Eye Irrit. 2 H319 Causes serious eye irritation.



**2.2 Label elements**

Symbol(s)

Indication(s) of danger

Risk phrase(s)

Safety advices

**WARNING**

H317 May cause an allergic skin reaction.

H319 Causes serious eye irritation.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P264 Wash hands thoroughly after handling.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P302+P352 IF ON SKIN: wash with plenty of water/soap.

P305+P351+P338 IF IN EYES: rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P337+P313 If eye irritation persists: get medical advice/attention.

P333+P313 If skin irritation or rash occurs: get medical advice/attention.

P501 Dispose of contents/container to an authorized center.

EUH208 Contains eugenol. May produce an allergic reaction.

Not available

**2.3 Other hazards**

**3. COMPOSITION/INFORMATION ON**

**INGREDIENTS**

**Chemical nature**

**Liquid**

Chemical name (Concentration %)			
CAS Nb	EC Nb	Index	Classification
1272/2008/CE (CLP)			
EUGENOL (> 80%)			
97-53-0	202-589-1	-	Skin Sens. 1 H317 Eye Irrit. 2 H319
CANADIAN BALSAM (1.5 - 15%)			
8007-47-4	232-362-2	-	Flam. Liq. 2 H226

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**4. FIRST AID MEASURES**

**4.1 Description of the first aid measures**

Inhalation	Remove to fresh air. In case of unconsciousness lie down and move the patient in stable side position. Seek medical advice.
Contact with skin	Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, seek medical attention.
Contact with eyes	Irrigate copiously with clean, fresh water for at least 15 minutes keeping the eyelids opened. Seek medical advice.
Ingestion	Do not drink, do not induce vomiting, seek medical advice.

**4.2 Most important symptoms and effects, both acute and delayed**

Not available

**4.3 Indications of possible immediate medical attention and particular treatment needed**

Not available

**5. FIREFIGHTING MEASURES**

**5.1 Extinguishing media**

Suitable extinguishing media All are suitable.

**5.2 Special hazards resulting from substance or mixture**

Toxic gazes can be involved under fire conditions: carbon monoxide and carbon dioxide.

**5.3 Advice to firefighters**

Use self-contained breathing apparatus

**6. ACCIDENTAL RELEASE MEASURES**

**6.1 Individual precautions, protection equipment and emergency procedures**

Basic precautions	Wear gloves and suitable goggles. Do not breath vapours. Keep away from sources of ignition.
Means of protection	Consult section 8

**6.2 Environmental precautions**

Do not dump into drains

**6.3 Methods and material of confinement and cleaning up**

Absorb with an inert material (sand, vermiculite). Wash the soiled area with water

**6.4 Reference to other sections**

Consult section 8 for personal protection  
Consult section 13 for disposal conditions

**7. HANDLING AND STORAGE**

**7.1 Precautions for safe handling**

Keep out of reach of children. Do not swallow. Avoid contact with skin and eyes. Close well the bottle after use. Wash hands thoroughly after handling. Wash soiled clothing before reuse.  
Comply with conditions of use.

**7.2 Conditions for safe storage, including any incompatibilities**

Conditions of storage Keep in the original container, tightly closed, at a temperature between + 5°C and + 25°C protected from moisture.

**7.3 Special end use(s)**

Product for professional dental use

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

**8.1 Control parameters**

Contains no substances with occupational exposure limits.

**8.2 Exposure controls**

Respiratory protection	Not necessary under normal conditions of use.
Hand protection	Wear appropriate gloves
Eye/face protection	Wear protective goggles
Skin and body protection	Wear safety clothing. Wash hands after use. Do not eat, drink or smoke during use

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**9. PHYSICAL AND CHEMICAL PROPERTIES**

**9.1 Information on basic physical and chemical properties**

Appearance	Liquid
Color	Yellow
Odour	Characteristic of clove
pH	7.4
Relative density at 20°C	1.05

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**10. STABILITY AND REACTIVITY**

<b>10.1 Reactivity</b>	Not available
<b>10.2 Chemical stability</b>	Chemically stable under normal conditions of use. The product may darken over time without altering the characteristics.
<b>10.3 Possibility of hazardous reactions</b>	None known.
<b>10.4 Conditions to avoid</b>	Light, heat.
<b>10.5 Incompatible materials</b>	Iron, rubber
<b>10.6 Hazardous decomposition products</b>	Not available

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**11. TOXICOLOGICAL INFORMATION**

**11.1 Information on toxicological effects**

Acute toxicity	Eugenol LD <sub>50</sub> (rat) : 2.68g/kg
Irritation	May cause skin irritation.
Sensitization	May cause sensitization by skin contact.

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**12. ECOLOGICAL INFORMATION**

<b>12.1 Toxicity</b>	Not available
<b>12.2 Persistence and degradability</b>	Not available
<b>12.3 Bioaccumulation potential</b>	Not available
<b>12.4 Mobility in the soil</b>	Not available
<b>12.5 Results of PBT and vPvB assessments</b>	Not available
<b>12.6 Other adverse effects</b>	Not available

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**13. DISPOSAL CONSIDERATIONS**

<b>13.1 Waste treatment methods</b>	Do not dump residue into drain. The chemicals must be eliminated according to applicable regulations. Packaging of chemical products must be eliminated according to applicable regulations.
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**14. TRANSPORT INFORMATION**

Not regulated.

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**15. REGULATORY INFORMATION**

<b>15.1 Special regulations/legislation for substance or mixture in terms of safety, health and environment</b>	Medical device in class IIa according to directive 93/42/EEC
<b>15.2 Chemical safety evaluation</b>	Not available

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**16. OTHER INFORMATION**

**Successive modifications:**

Version 1 of 10/10/2008 : Creation

Version 2 of 10/10/2012 : Changes according to regulation EC 453/2010 annex I

Version 3 of 12/12/2014 : Changes according to CLP 1272/2008/EC

Version 4 of 08/10/2020 : The font and the text size and the title « SAFETY DATA SHEET According to 1907/2006/EC, Article 31 »

**Product: SEALITE LIQUIDE**

SDS No. 266267

Created on: 10/10/2008

Updated on: 08/10/2020

**Abbreviations:**

Skin Sens. 1 H317 May cause an allergic skin reaction.

Eye Irrit. 2 H319 Causes serious eye irritation.

Flam. Liq. 2 H226 Flammable liquid and vapour.

**Recommended restrictions on use**

CAUTION: Product intended exclusively for professional dental use

**Other information**

This sheet complements the technical sheets but does not replace them.

The information that is contained herein is based on the state of our knowledge related to the product concerned at the date of issue and is given in good faith. Moreover, the user's attention is drawn to the possible risks incurred by using the product for any other use than that for which it was intended.

With the present, the user is not dispensed to know and to apply the whole regulating text of activity. He should be responsible for all precautions relating to the use of his product.

The whole regulation prescription mentioned is simply to help the user to fulfill the obligations in the use of hazardous product. This enumeration must not be considered as exhaustive. The user is not exempted to secure than those cited concerning the detention and the manipulation of product for which he is alone responsible.

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**Product: SEALITE REGULAR**

SDS No. 266264

Created on: 10/10/2008

Updated on: 08/10/2020

**1. IDENTIFICATION OF THE SUBSTANCE / MIXTURE AND OF THE COMPANY / UNDERTAKING**

**1.1 PRODUCT identification**

**SEALITE REGULAR**

**1.2 Relevant use of mixture**

Permanent sealing cement for root canals

**1.3 Information concerning safety data sheet supplier**

PRODUITS DENTAIRE PIERRE ROLLAND SAS

Address Z.I. du Phare - 17 avenue Gustave Eiffel - 33700 MERIGNAC - FRANCE

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**EMERGENCY CALL NUMBER**

**2. HAZARDS IDENTIFICATION**

**2.1 Classification of substance or mixture**

According to Regulation 1272/2008/EC



Skin Sens. 1  
Aquatic Acute 1

Skin sensitization, category 1 (H317)  
Hazardous to the aquatic environment - Acute hazard, category 1 (H400)

Aquatic Chronic 1

Hazardous to the aquatic environment - Chronic hazard, category 1 (H410)

**2.2 Label elements**

Symbol(s)



Indication(s) of danger

Risk phrase(s)

Safety advices

**WARNING**

H317 May cause an allergic skin reaction.

H400 Very toxic to aquatic life.

H410 Very toxic to aquatic life with long lasting effects.

P261 Avoid breathing dust/fume/gas/mist/vapours/spray.

P333+P313 If skin irritation or rash occurs: get medical advice/attention.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P273 Avoid release to the environment.

P391 Collect spillage.

P501 Dispose of contents/container to an authorized center.

EUH208 Contains diiodothymol and rosin. May produce an allergic reaction.

Handling this substance can potentially generate dust formation that can cause mechanical irritation of eyes, skin, nose and throat

**2.3 Other hazards**

**3. COMPOSITION/INFORMATION ON**

**INGREDIENTS**

**Powder**

**Chemical nature**

Chemical name (Concentration %)			
CAS Nb	EC Nb	Index	Classification
ZINC OXIDE (40-50%)			
1314-13-2	215-222-5	030-013-00-7	Aquatic Acute 1 H400 Aquatic Chronic 1 H410
HYDROGENATED ROSIN (≈ 15%)			
8050-09-7	232-475-7	650-015-00-7	Skin Sens. 1 H317
DIIODOTHYMOL (≈ 15%)			
552-22-7	209-007-5		Skin Sens. 1 H317 Acute Tox. 4 H302

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**4. FIRST AID MEASURES**

**4.1 Description of the first aid measures**

Inhalation	Remove to fresh air. In case of unconsciousness lie down and transport the patient in stable side position. Seek medical advice.
Contact with skin	Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, seek medical attention.
Contact with eyes	Irrigate copiously with clean, fresh water for at least 15 minutes keeping the eyelids opened. Seek medical advice.
Ingestion	Rinse mouth with plenty of water. Do not drink, do not induce vomiting, seek a medical advice.

**4.2 Most important symptoms and effects, both acute and delayed**

Not available

**4.3 Indications of possible immediate medical attention and particular treatment needed**

Not available

**5. FIREFIGHTING MEASURES**

**5.1 Extinguishing media**

Suitable extinguishing media All are suitable.

**5.2 Special hazards resulting from substance or mixture**

Decomposition products may be formed under fire: oxide / metal oxide

**5.3 Advice to firefighters**

Use self-contained breathing apparatus

**6. ACCIDENTAL RELEASE MEASURES**

**6.1 Individual precautions, protection equipment and emergency procedures**

Basic precautions	Wear gloves and suitable goggles. Do not breath vapours. Keep away from sources of ignition.
Means of protection	Consult section 8

**6.2 Environmental precautions**

Do not dump into drains. Material able to pollute the water. May be harmful to the environment if released in large quantities. Collect spillage.

**6.3 Methods and material of confinement and cleaning up**

Vacuum or collect spillage with a broom. Place spillage in a labeled waste container. Disposal by a licensed waste collection company.

**6.4 Reference to other sections**

Consult section 8 for personal protection  
Consult section 13 for disposal conditions

**7. HANDLING AND STORAGE**

**7.1 Precautions for safe handling**

Keep out of reach of children. Avoid contact with skin and eyes. Keep away from sources of ignition. Do not swallow. Wash your hands thoroughly after handling. Avoid breathing dust. Wash soiled clothing before reuse.  
Comply with conditions of use

**7.2 Conditions for safe storage, including any incompatibilities**

Conditions of storage Close immediately and tightly after use. Keep in the original container, tightly closed, at a temperature between + 5°C and + 25°C protected from moisture and light.

**7.3 Special end use(s)**

Product for professional dental use

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**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

**8.1 Control parameters**

Zinc oxide (dust):  
 . France /Belgium/Spain TLV 10mg/m<sup>3</sup>  
 . Germany TLV 4 inhalable aerosol mg/m<sup>3</sup>  
 Rosin: UK TLV 0.05 mg/m<sup>3</sup>

**8.2 Exposure controls**

Respiratory protection If exposure to dust or fumes: wear FFP2 mask protection.  
 Hand protection Wear appropriate impervious gloves  
 Eye/face protection Wear protective goggles  
 Skin and body protection Wear safety clothing. Wash hands after use. Do not eat, drink or smoke during use

**9. PHYSICAL AND CHEMICAL PROPERTIES**

**9.1 Information on basic physical and chemical properties**

Appearance Powder  
 Color Slightly grey  
 Odour Iodine  
 pH Not applicable

**10. STABILITY AND REACTIVITY**

**10.1 Reactivity** Not available  
**10.2 Chemical stability** Chemically stable under normal conditions of use.  
**10.3 Possibility of hazardous reactions** None according to our knowledge.  
**10.4 Conditions to avoid** Not available  
**10.5 Incompatible materials** Reactive or incompatible with acids and alkalis.  
**10.6 Hazardous decomposition products** Not available

**11. TOXICOLOGICAL INFORMATION**

**11.1 Information on toxicological effects**

Acute toxicity LD<sub>50</sub> zinc oxide (rat) > 5000 mg/kg  
 Irritation Frequent contact and prolonged skin contact may cause skin irritation  
 Sensitization May cause sensitization by skin contact

**12. ECOLOGICAL INFORMATION**

	Zinc oxide	Results	Exposure
<b>12.1 Toxicity</b>	Algae -Selenastrum Capricornutum	Aigue EC50 0.17mg/L	72 hours
	Daphnia -Daphnia magna	Aigue EC50 1mg/L fresh water	48 hours
	Algae - Pseudokirchneriella subcapitata - exponential growth phase	Chronic NOEC 0.4mg/L fresh water	72 hours

**12.2 Persistence and degradability** Not available  
**12.3 Bioaccumulation potential** Log Pow = 2.2 for zinc oxide  
**12.4 Mobility in the soil** Not available  
**12.5 Results of PBT and vPvB assessments** Not applicable

**12.6 Other adverse effects** Known according to our knowledge

**Product: SEALITE REGULAR**

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**13. DISPOSAL CONSIDERATIONS**

**13.1 Waste treatment methods**

Do not dump residue into drain. The chemicals must be eliminated in keeping with applicable regulations.  
Packaging of chemical products must be eliminated in keeping with applicable regulations.

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**14. TRANSPORT INFORMATION**

**UN 3077 : HAZARDOUS MATERIAL FOR THE ENVIRONMENT, SOLID, NOS (zinc oxide)**

ADR : Class 9 Packing group III

IMDG : Class 3 Packing group III

IATA : Class 3 Packing group III

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**15. REGULATORY INFORMATION**

**15.1 Special regulations/legislation for substance or mixture in terms of safety, health and environment**

Medical device in class III according to directive 93/42/EEC

**15.2 Chemical safety evaluation**

Not available

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**16. OTHER INFORMATION**

**Successive modifications:**

Version 1 of 10/10/2008 : Creation

Version 2 of 04/07/2013 : Changes according to regulation EC No. 453/2010 annex 1

Version 3 of 11/12/2014 : Changes according to CLP 1272/2008/EC

Version 4 of 08/10/2020 : The font and the text size and the title « SAFETY DATA SHEET According to 1907/2006/EC, Article 31 »

**Abbreviations:**

**Skin Sens. 1.** H317 May cause an allergic skin reaction.

**Aquatic Acute 1.** H400 Very toxic to aquatic life.

**Aquatic Chronic 1.** H410 Very toxic to aquatic life with long lasting effects.

Acute Tox. 4 H302 Harmful if swallowed.

**Recommended restrictions on use**

CAUTION: Product intended exclusively for professional dental use

**Other information**

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