

**Product: HEMOSTASYL**

SDS No. 246200

Created on: 02/02/2007

Updated on: 29/04/2015

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

**1.1 PRODUCT identification**

**HEMOSTASYL**

**1.2 Relevant use of mixture**

Haemostatic dressing with mechanical action

**1.3 Information concerning safety data sheet supplier**

PRODUITS DENTAIRE PIERRE ROLLAND SAS

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**EMERGENCY CALL NUMBER**

<http://echa.europa.eu/web/guest/support/helpdesks/national-helpdesks/list-of-national-helpdesks>

**2. HAZARDS IDENTIFICATION**

**2.1 Classification of substance or mixture**

According to Regulation 1272/2008/EC The product is not classified as hazardous according to regulation (EC) 1272-2008 (CLP) and subsequent amendments.

**2.2 Label elements**

Symbol(s) None  
 Indication(s) of danger None  
 Risk phrase(s) None  
 Safety advices Keep out of the reach of children  
 Avoid contact with eyes  
 Contains Aluminium chloride hexahydrate

**2.3 Other hazards**

None

**3. COMPOSITION /INFORMATION ON INGREDIENTS**

**Chemical nature** Paste

**MIXTURE**

<i>Chemical name (Concentration %)</i>				
<i>CAS Nb</i>	<i>EC Nb</i>	<i>Index</i>	<i>Classification</i>	<i>Classification</i>
Aluminium chloride hexahydrate (15%)				
7784-13-6	-	-	Xi R36/37/38	Skin Irrit. 2H315 Eye Irrit. 2 H319 STOT SE 3 H335
Kaolin (40%)				
1332-58-7	310-194-1	-	-	

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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 place patient stably in side position for transportation. Seek medical advice.
Contact with skin	Remove contaminated clothing. Wash immediately with plenty of water. If irritation persists, seek medical advice.
Contact with eyes	Irrigate copiously with clean, fresh water at least 15 minutes keeping the eyelids opened. If symptoms persist, consult ophthalmologist.
Ingestion	Do not induce vomiting, rinse mouth with water. If digestive symptoms persist, 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 extinguishing media are suitable

**5.2 Special hazards resulting from substance or mixture** Do not breathe combustion products

**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.

**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. Avoid contact with skin and eyes. Do not swallow.  
 Wash your hands thoroughly after handling.  
 Wash soiled clothing before reuse.  
 Comply with conditions of use.

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

**Conditions of storage** Keep the product in its original pack, tightly closed away from light. Store away from heat and at a temperature between 5 -25°C.

**7.3 Special end use(s)** Product for professional dental use

**8. EXPOSURE CONTROLS / PERSONAL PROTECTION**

**8.1 Control parameters**

Substance	Eta t	TWA/8 h		STEL/15 min	
		mg/m <sup>3</sup>	pp m	mg/m <sup>3</sup>	pp m
Kaolin	Fr	10 respirable aerosol		10	
	B	2 respirable aerosol			
	UK	2 respirable aerosol			
	DK	2 respirable aerosol		4 respirable aerosol	

**8.2 Exposure controls**

**Respiratory protection** Not necessary in 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.

**9. PHYSICAL AND CHEMICAL PROPERTIES**

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

Appearance Paste  
 Color Blue  
 Odour Strawberry  
 pH Not applicable  
 Relative density at 20°C Not available

**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.  
**10.4 Conditions to avoid** Light, heat. Do not mix with other products.  
**10.5 Incompatible materials** Information not available  
**10.6 Hazardous decomposition products** In case of fire, risk of formation of hydrochloric acid.

**11. TOXICOLOGICAL INFORMATION**

**11.1 Information on toxicological effects**

*Skin contact* After prolonged contact, no irritation appears.  
 Risk of allergic reaction due to aluminium chloride.

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**12. ECOLOGICAL INFORMATION**

**12.1 Toxicity** Not available

**12.2 Persistence and degradability** Not available

**12.3 Bioaccumulation potential** Not available

**12.4 Mobility in the soil** Not available

**12.5 Results of PBT and vPvB** Not available

**assessments**

**12.6 Other adverse effects** Not available

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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**

The product is not a hazardous product according to the regulations applicable to transport

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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 IIa 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 02/02/2007 : Created

Version 2 of 09/10/2012 : Changes according to regulation EC No. 453/2010 annex 1.

Version 3 of 24/05/2013 : Correction of an error relating to classification of propylene glycol

Version 4 of 09/12/2013 : Modification of emergency number

Version 5 of 29/04/2015 : Changes according to CLP 1272/2008/EC

**Abbreviations:**

Skin irrit. 2H315: Cause skin irritation.

Eye irrit. 2H319: Cause serious eyes irritation.

STOT SE 3 H335: Irritating to respiratory tract.

**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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