

## SAFETY DATA SHEET According to regulation (EC) No. 453/2010 annex I

Product: HEMOSTASYL

SDS No. 246200 Created on: 02/02/2007 Updated on: 09/12/2013

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

1.1 PRODUCT identification HEMOSTASYL

Haemostatic dressing with mechanical action 1.2 Relevant use of mixture

1.3 Information concerning safety data sheet

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**EMERGENCY CALL NUMBER** http://echa.europa.eu/web/guest/support/helpdesks/national-

helpdesks/list-of-national-helpdesks

PRODUITS DENTAIRES PIERRE ROLLAND

2. HAZARDS IDENTIFICATION

2.1 Classification of substance or mixture

In conformity with the directives 67/548/EEC, 1999/45/EC and adaptations of them

The product is not classified as hazardous pursuant to the provisions set forth in Directives 67/548/CE and 1999/45/CE or EC regulation 1272/2008/CLP and subsequent amendments and supplements.

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2.2 Label elements

Symbol(s) None Indication(s) of danger None Risk phrase(s)

S2: Keep out of the reach of children Safety advices

S25: Avoid contact with eyes Aluminium chloride hexahydrate

2.3 Other hazards None

3. COMPOSITION /INFORMATION ON INGREDIENTS

Chemical nature **Paste** 

**MIXTURE** 

Contains

Chemical name (Co	ncentration %)			
CAS Nb	EC Nb	Index	Classification 67/548/EEC	Classification 1272/2008/CE (CLP)
Aluminium chloride hexahydrate (15%)				
7784-13-6	-	-	Xi R36/37/38	Skin Irrit. 2H315 Eye Irrit. 2 H319 STOT SE 3 H335

### 4. FIRST AID MEASURES

### 4.1 Description of the first aid measures

Remove to fresh air. In case of unconsciousness place patient stably in side Inhalation

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.

Do not induce vomiting, rinse mouth with water. If digestive symptoms Ingestion

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



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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.

Consult section 8. Means of protection

Do not dump into drains. 6.2 Environmental

precautions

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.

### 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

Contains no substances with occupational exposure limit values

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 REACTIVTY

10.1 Reactivity Not available

10.2 Chemical stability Chemically stable under normal conditions of use.

10.3 Possibility of hazardous None.

reactions

10.4 Conditions to avoid Light, heat. Do not mix with other products.

10.5 Incompatible materials Information not available

10.6 Hazardous In case of fire, risk of formation of hydrochloric acid.

decomposition products



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### 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.

### 12. ECOLOGICAL INFORMATION

**12.1 Toxicity** Not available

12.2 Persistence and

degradability

Not available

12.3 Bioaccumulation

Not available

potential

12.4 Mobility in the soil Not available12.5 Results of PBT and vPvB Not available

assessments

methods

12.6 Other adverse effects Not available

### 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment

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.

#### 14. TRANSPORT INFORMATION

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

### 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

### 16. OTHER INFORMATION

### Successive modifications:

Version 1 of 02/02/2007: Created

Version 2 of 09/10/2012: Changes according to CLP 1272/2008/EC

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

### Abbreviations:

Skin irrit. 2H315: Cause skin irritation.

Eye irrit. 2H319: Cause serious eyes irritation. STOT SE 3 H335: Irritating to respiratory tract.

Xi: Irritating

R36/37/38: Irritating to eyes, respiratory system and skin.

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.

End of the document.