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

**Product: EXPASYL** SDS No. 261030/294010 Created on: 27/11/1998 Updated on: 24/03/2015

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

1.1 PRODUCT identification EXPASYL

**1.2 Relevant use of mixture** Paste for gingival retraction

1.3 Information concerning safety data

sheet supplier

PRODUITS DENTAIRES PIERRE ROLLAND SAS

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EMERGENCY CALL NUMBER http://echa.europa.eu/web/quest/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 - kaolin

**2.3 Other hazards** Not available

# 3. COMPOSITION /INFORMATION ON INGREDIENTS

Chemical nature Paste

# **MIXTURE**

Chemical name (0	Concentration %)		
CAS Nb	EC Nb	Index	Classification
			1272/2008/CE (CLP)
Aluminium chlor	ride hexahydrate (15	%)	
7784-13-6	-	-	Skin Irrit. 2H315
			Eye Irrit. 2 H319
			STOT SE 3 H335
Kaolin (70%)			
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. Consult doctor.

Contact with skin Remove contaminated clothing. Wash immediately with plenty

of water. If irritation persists, consult doctor.

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, consult doctor.

4.2 Most important symptoms and effects, both acute and delayed

4.3 Indications of possible immediate

medical attention and particular

Not available

Not available

treatment needed

#### **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, sewer systems, surface water, ground

water and confined areas.

# 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

8.2 Exposure controls

	Eta	TWA/8 h		STEL/15 min	
Substance	Eta	mg/m³	рр	mg/m³	рр
			m		m
Kaolin	Fr	10 respirable		10	
		aerosol			
	В	2 respirable			
		aerosol			
	UK	2 respirable			
		aerosol			
	DK	2 respirable		4 respirable	
		aerosol		aerosol	

**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 Green

Odour None

pH Not applicable

Relative density at 20°C Not available

#### 10. STABILITY AND REACTIVTY

Not available 10.1 Reactivity

**10.2 Chemical stability** Chemically stable under normal conditions of use.

No hazardous reactions are foreseeable in normal condition of use. 10.3 Possibility of

hazardous 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

### 11. TOXICOLOGICAL INFORMATION

#### 111.1 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

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.

## 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 I according to directive 93/42/EEC

**15.2 Chemical safety evaluation** Not available

# **16. OTHER INFORMATION**

Successive modifications:

Version 1 of 27/11/1998: Created

Version 2 of 11/06/2009: Updating of chap no. 13

Version 3 of 09/10/2012: Changes according to regulation EC No. 453/2010 annex 1.

Version 4 of 20/05/2014: Updating of emergency number and control parameters (chap 8).

Version 5 of 24/03/2015: Changes according to CLP 1272/2008/EC.

# **Abbreviations:**

Skin irrit. 2H315: Cause skin irritation.

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

**Recommended restrictions on use**CAUTION: Product intended exclusively for professional dental use



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# 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.