

Product: EXPASYL Exact
SDS No. 261 010 / 261 011 / 299 235 / 299 221
Created on: 11/02/2020
Updated on: 29/06/2020

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

1.1 PRODUCT identification	EXPASYL Exact
1.2 Relevant use of mixture	Paste for gingival retraction
1.3 Information concerning safety data sheet supplier	PRODUITS DENTAIRES PIERRE ROLLAND SAS
<i>Address</i>	Z.I. du Phare – 17 avenue Gustave Eiffel - 33700 MERIGNAC - FRANCE
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<i>Phone:</i>	+ 33 (0)5 56.34.06.07
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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

The product is not classified as dangerous in accordance with the provisions of Regulation (EC) 1272-2008 (CLP) and subsequent amendments. However, containing dangerous substances at a concentration as to be declared in section 3, the product requires a safety data sheet containing appropriate information, in accordance with Regulation (EC) 1907/2006 and subsequent amendments.

2.2 Label elements

Regulation EC 1272/2008, relating to the classification, labeling and packaging of substances and mixtures (CLP), does not apply to medical devices in the finished state used in direct physical contact with the human body according to what is dictated by art. 1.5, paragraph d). The product is therefore exempted from the CLP labeling requirement.

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	Aluminum chloride hexahydrate - kaolin
2.3 Other hazards	Not available

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>
Aluminium chloride 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 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, 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.

7.2 Conditions for safe storage, including any incompatibilities

Conditions of storage Store in the original packaging, tightly closed and protected from light.
Store in a place away from heat, at a temperature between 5 and 25 ° C.

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

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 Control parameters

Substance	Etat	TWA/8 h		STEL/15 min	
		mg/m ³	ppm	mg/m ³	ppm
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 Green

Odour None

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 No hazardous reactions are foreseeable in normal condition of use.

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.

12. ECOLOGICAL INFORMATION

12.1 Toxicity Not available

12.2 Persistence and degradability Not available

12.3 Bioaccumulation potential Not available

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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 11/02/2020: Created

Version 2 of 29/06/2020: Addition of product reference N°299 221.

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

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.