

Product: FRILIET

SDS no 239803 Created: 04/06/1998 Updated: 18/11/2015

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

1.1 PRODUCT identification **FRILIET**

1.2 Relevant use of mixture Cryoanaesthesia - Pulp vitality test

1.3 Information concerning safety data sheet PRODUITS DENTAIRES PIERRE ROLLAND SAS

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2. HAZARDS IDENTIFICATION

2.1 Classification of substance or mixture

In conformity with the regulation 1272/2008/EC



WARNING

H223 Flammable aerosol

H229 Pressurised container: may burst if heated

2.2 Label elements

Symbol(s)



Indication(s) of danger WARNING

Risk phrase(s) H223 Flammable aerosol

H229 Pressurised container: may burst if heated.

Safety advices P210 Keep away from heat, hot surfaces, sparks, open flames and other

ignition sources. No smoking.

P211 Do not spray on an open flame or other ignition source

P251 Do not pierce or burn, even after use.

P410 Protect from sunlight.

P412 Do no expose to temperatures exceeding 50°C/122°F.

Contains Tetrafluoroethane and ethanol

2.3 Other hazards Warning: this product induces a fall in the tissues temperature until - 25°C

> and can cause tissues necrosis if the instructions for use are not respected. For topical use only: limit the zone of application in the mouth. Avoid spraying onto damaged mucosa (presence of ethanol). Do not breathe the

aerosol. Do not spray upside down. Do not spray towards the eyes.

3. COMPOSITION /INFORMATION ON INGREDIENTS

Chemical nature SUBSTANCE

Liquid

| CAS No | CE No | Index No | Classification |
|---------------|-----------|--------------|-------------------|
| | | | 1272/2008/CE |
| Ethanol (95%) | | | |
| 64-17-5 | 200-578-6 | 603-002-00-5 | Flam. Liq. 2 H225 |
| Norflurane | | | |
| 811-97-2 | 212-377-0 | - | - |



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4. FIRST AID MEASURES

4.1 Description of the first aid measures

Inhalation Remove victim to fresh air. Artificial respiration if necessary. In case of collapse,

avoid using epinephrine medicines.

Contact with skin In case of frostbite, treat as thermal burns.

Contact with eyes Wash immediately with plenty of water keeping the eyelids opened. 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

Not available

needed

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media All are suitable.

5.2 Special hazards resulting from FLAMMABLE.

substance or mixture

Thermal decomposition may liberate toxic and corrosive products: hydrogen

fluoride and carbon oxide.

5.3 Advice to firefightersUse 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 breathe vapours. In a closed room,

ventilate or wear a self-contained breathing apparatus. Take away from all ignition sources. Do not smoke.

Means of protection Refer to section 8.

6.2 Environmental precautions

Do not dispose of in the environment.

6.3 Methods and material of confinement and cleaning up

Absorb with an inert material (sand, vermiculite). Wash contaminated 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 the skin and eyes.

Do not swallow. Do not breathe vapours. Wash carefully hands after handling. Wash soiled clothing before reuse. Respect the instructions for use.

Instructions applicable to pressurized containers: prohibit ignition sources and contact with hot surfaces. NO SMOKING. Respect the instructions for use.

7.2 Conditions for safe storage, including any incompatibilities

Conditions of storage Keep the product in its original pack.

Instructions applicable to pressurized containers: store in a fresh and well-

ventilated area, away from heat, sources of ignition, naked flames, hot surfaces and

sources of inflammation.



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Protect the full packing from sources of heat to avoid overpressure.

Store in an area away from heat, at a temperature between + 5°C and + 25°C.

Product for dental professional use

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

ETHANOL TLV: 8.1 Control parameters

> France 5000ppm (9500mg/m³) Germany 1000ppm (1950mg/m³) United Kingdom 1000ppm (1950mg/m³)

Spain 1000ppm (1950mg/m³)

8.2 Exposure controls

7.3 Special end use(s)

Recommended if insufficient ventilation. Do not breathe vapours. Respiratory protection

Wear appropriate gloves Hands protection Eyes protection Wear protective goggles. Skin and body protection Wear safety clothing. Wash hands after handling.

Do not eat, drink or smoke while using.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Liquefied gas **Appearance** Colourless Colour Odour Mint

рΗ Not applicable Boiling point - 26°C

10. STABILITY AND REACTIVITY

Not available 10.1 Réactivity

Chemically stable under normal conditions of use. 10.2 Chemical stability

10.3 Possibility of hazardous reactions None known 10.4 Conditions to avoid Light, heat. 10.5 Incompatible materials Not available

10.6 Hazardous decomposition products Thermal decomposition may liberate toxic and corrosive products: hydrogen

fluoride and carbon oxide.

11. TOXICOLOGICAL INFORMATIONS

11.1 Informations on toxicological effects

Swallowing Experiment on animals: practically not harmful by inhalation.

LC50/inhalation/4h/rat > 500 000 ppm.

Vapours inhalation Like other volatile aliphatic halogenated compounds, the product may cause

accumulation of vapors and / or inhalation of large quantities: loss of consciousness

and cardiac disorders aggravated by stress and lack of oxygen.

Splashing in the eyes A little or no irritating to eyes

12. ECOLOGICAL INFORMATION

12.1 Toxicity Uneasily biodegradable in water: 3% after 28 days.

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 assessments Not available 12.6 Other adverse effects Not available



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13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methodsDo not dump residue into drain. Chemical products must be eliminated in keeping

with applicable regulations.

Packaging of chemical products must be eliminated in keeping with applicable

regulations.

14. TRANSPORT INFORMATION

UN number UN 1950 AEROSOL 2.1
Shipping name AEROSOL, FLAMMABLE

Road transport ADR/RID

Class 2 5F GAZ
Classification code and packing group 2.1

Maritimes transport IDMG

Class 2 AEROSOL Packing group 2.1

Air transport IATA/ICAO

Class AEROSOL, FLAMMABLE 2

Packing group 2.

15. REGULATORY INFORMATION

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

Regulation (EU) No 487/2013 of the Committee on 8th May 2013 amending Regulation (EC) No 1272/2008 of the European Parliament and the Council of 16th December 2008 on classification, labeling and packaging of substances and mixtures amending and repealing Directives 67/548/EEC and 1999/45/EC and

amending regulation (EC) No 1907/2006.

Medical device class IIa according to 93/42/EEC directive

15.2 Chemical safety evaluation Not available

16. OTHER INFORMATION

Successives modifications:

Version 1 of 06/1998: Created

Version 2 of 21/05/2010: Highly flammable aerosol classification

Version 3 of 09/11/2015 : Changes according to regulation EC 453/2010 - Classification flammable aerosol Version 4 of 06/11/2015: Changes according to CLP 1272/2008/CE - Classification flammable aerosol

Abbreviations:

H223 Flammable aerosol.

H229 Pressurised container: may burst if heated.

P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.

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P412 Do no expose to temperatures exceeding 50°C/122°F.

Recommended restrictions on useCAUTION: Product intended exclusively for professional dental use

Other informations

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.