

## Safety data sheet

According to 1907/2006/EC, Article 31

Printing date 22.08.2018

Version number 2

Revision: 22.08.2018

### SECTION 1: Identification of the substance/mixture and of the company/undertaking

· **1.1 Product identifier**

· **Trade name:** *STERIMAR Hygiène et confort du nez*

· **1.2 Relevant identified uses of the substance or mixture and uses advised against**

*No further relevant information available.*

· **Application of the substance / the preparation :** *Medical device*

· **1.3 Details of the supplier of the safety data sheet**

· **Manufacturer/Supplier:**

*SOFIBEL – Laboratoires Fumouze*

*110-114 rue Victor Hugo, 92686 LEVALLOIS-PERRET Cedex*

*Tel : +33 1 49 68 42 42 – Fax +33 1 49 68 41 01*

· **1.4 Emergency telephone number:**

*France (INRS 24h/24) - Tel : +33 (0)1 45 42 59 59*

*Ireland - Tel : 00 353 1 8092568 - 00 353 1 8379964 (24h/24) EU Tel: 112*

*Belgique - Tel : 32 070/245 245*

*UK : Call NHS 999 in a medical emergency. If you urgently need medical help or advice but it's not a life-threatening situation, call 111 (24/7). The NHS 111 number is currently only available in certain areas. If you're outside of these areas, you should call NHS Direct on 0845 4647*

### SECTION 2: Hazards identification

· **2.1 Classification of the substance or mixture**

· **Classification according to Regulation (EC) No 1272/2008 :**

*Aerosol 3 H229 Pressurised container: May burst if heated.*

· **2.2 Label elements**

· **Labelling according to Regulation (EC) No 1272/2008**

*The product is classified and labelled according to the CLP regulation.*

· **Hazard pictograms** *Not classified as hazardous*

· **Signal word** *Warning*

· **Hazard statements**

*H229 Pressurised container: May burst if heated.*

· **Precautionary statements**

*P101 If medical advice is needed, have product container or label at hand.*

*P102 Keep out of reach of children.*

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

*P251 Do not pierce or burn, even after use.*

*P410+P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.*

· **2.3 Other hazards**

· **Results of PBT and vPvB assessment**

· **PBT:** *Not applicable.*

· **vPvB:** *Not applicable.*

### SECTION 3: Composition/information on ingredients

· **3.2 Chemical characterisation: Mixtures**

· **Description:** *Mixture: consisting of the following components.*

· **Dangerous components:** *Not classified as hazardous*


· **Other components:**

*CAS: 7727-37-9*

*EINECS: 231-783-9*

*RTECS: QW 9700000*

*nitrogen*

 *Press. Gas (Ref. Liq.), H281*

· **SVHC** *No*

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 · **Additional information:** For the wording of the listed risk phrases, refer to section 16.

#### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **General information:** No special measures required.
- **After excessive inhalation:** No special measures required
- **After skin contact:**  
No special measures required  
Generally the product does not irritate the skin.
- **After eye contact:** No special measures required
- **After swallowing:** No special measures required
- **4.2 Most important symptoms and effects, both acute and delayed :**  
No further relevant information available.
- **4.3 Indication of any immediate medical attention and special treatment needed :**  
No further relevant information available.

#### SECTION 5: Firefighting measures

- **5.1 Suitable extinguishing agents:** Product is not flammable
- **5.2 Special hazards arising from the substance or mixture :** No further relevant information available.
- **5.3 Advice for firefighters**
- **Protective equipment:** No special measures required.

#### SECTION 6: Accidental release measures

- **6.1 Personal precautions, protective equipment and emergency procedures :** Not required.
- **6.2 Environmental precautions:** No special measures required.
- **6.3 Methods and material for containment and cleaning up:**  
Absorb with liquid-binding material (sand, diatomite, acid binders, universal binders, sawdust).
- **6.4 Reference to other sections :**  
See Section 7 for information on safe handling.  
See Section 8 for information on personal protective equipment.  
See Section 13 for disposal information.

#### SECTION 7: Handling and storage

- **7.1 Precautions for safe handling :** No special measures required.
- **Information about fire - and explosion protection:** No special measures required.
- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:** No special requirements.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
Protect from heat and direct sunlight.  
Protect from frost.
- **Recommended storage temperature:** <50°C
- **7.3 Specific end use(s) :** No further relevant information available.

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**SECTION 8: Exposure controls/personal protection**

- **Additional information about design of technical facilities:** No further data; see section 7.
- **8.1 Control parameters**
- **Ingredients with limit values that require monitoring at the workplace:**  
The product does not contain any significant quantities of materials with critical values that have to be monitored at the workplace.
- **Additional information:**  
The most current valid lists have been used as a basis for the production of this document.
- **8.2 Exposure controls**
- **Personal protective equipment:**
- **General protective and hygienic measures:**  
The usual precautionary measures are to be adhered to when handling chemicals.
- **Respiratory protection:** Not required.
- **Protection of hands:** Not required.
- **Gloves material :** -
- **Eye protection:** Not required.

**SECTION 9: Physical and chemical properties**

- **9.1 Information on basic physical and chemical properties**
- **General Information**
- **Appearance:**

<b>Form:</b>	Aerosol
<b>Colour:</b>	Colourless
<b>Odour:</b>	Odourless
<b>Odour threshold:</b>	Not determined.
- **pH-value at 20 °C:** 6.5-8.5
- **Change in condition**

<b>Melting point/freezing point:</b>	Undetermined.
<b>Initial boiling point and boiling range:</b>	Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gas):** Not applicable.
- **Ignition temperature:** Not applicable.
- **Decomposition temperature:** Not determined.
- **Auto-ignition temperature:** Product is not self igniting.
- **Explosive properties:** Product does not present an explosion hazard.
- **Explosion limits:**

<b>Lower:</b>	Not determined.
<b>Upper:</b>	Not determined.
- **Vapour pressure at 20 °C:** 6.2-8.2 bars
- **Density at 20 °C:** 1.003 g/cm<sup>3</sup>
- **Relative density :** Not determined.
- **Vapour density :** Not determined.
- **Evaporation rate :** Not determined.

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- |   |  |
|---|--|
| <b>· Solubility in / Miscibility with water:</b>    | Fully miscible.                            |
| <b>· Segregation coefficient (n-octanol/water):</b> | Not determined.                            |
| <b>· Viscosity:</b>                                 |  |
| <b>Dynamic:</b>                                     | Not determined.                            |
| <b>Kinematic:</b>                                   | Not determined.                            |
| <b>· Solvent content:</b>                           |  |
| <b>Water:</b>                                       | >98 %                                      |
| <b>· 9.2 Other information :</b>                    | No further relevant information available. |

### SECTION 10: Stability and reactivity

- **10.1 Reactivity** No further relevant information available.
- **10.2 Chemical stability**
- **Thermal decomposition / conditions to be avoided:** No decomposition if used according to specifications.
- **10.3 Possibility of hazardous reactions :** No dangerous reactions known.
- **10.4 Conditions to avoid :** No further relevant information available.
- **10.5 Incompatible materials:** No further relevant information available.
- **10.6 Hazardous decomposition products:** No dangerous decomposition products known.

### SECTION 11: Toxicological information

- **11.1 Information on toxicological effects**
- **Acute toxicity** Based on available data, the classification criteria are not met.
- **Primary irritant effect:**
- **On the skin:** Based on available data, the classification criteria are not met.
- **On the eyes:** Based on available data, the classification criteria are not met.
- **Respiratory or skin sensitization** Based on available data, the classification criteria are not met.
- **CMR effects (carcinogenicity, mutagenicity and toxicity for reproduction)**
- **Germ cell mutagenicity** Based on available data, the classification criteria are not met.
- **Carcinogenicity** Based on available data, the classification criteria are not met.
- **Reproductive toxicity** Based on available data, the classification criteria are not met.
- **STOT-single exposure** Based on available data, the classification criteria are not met.
- **STOT-repeated exposure** Based on available data, the classification criteria are not met.
- **Aspiration hazard** Based on available data, the classification criteria are not met.

### SECTION 12: Ecological information

- **12.1 Toxicity**
- **Aquatic toxicity:** No further relevant information available.
- **12.2 Persistence and degradability :** No further relevant information available.
- **12.3 Bioaccumulative potential :** No further relevant information available.
- **12.4 Mobility in soil :** No further relevant information available.
- **Additional ecological information:**
- **General notes:** Generally not hazardous for water.
- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.

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· 12.6 Other adverse effects : No further relevant information available.

**SECTION 13: Disposal considerations**

· 13.1 Waste treatment methods

· Recommendation : Smaller quantities can be disposed of with household waste.

· Uncleaned packaging:

· Recommendation: Disposal must be made according to official regulations.

· Recommended cleansing agents: Water, if necessary together with cleansing agents.

**SECTION 14: Transport information**

· 14.1 UN-Number

· ADR, IMDG, IATA UN1950

· 14.2 UN proper shipping name

· ADR UN1950 AEROSOLS  
· IMDG AEROSOLS  
· IATA AEROSOLS, non-flammable

· 14.3 Transport hazard class(es)

· ADR



· Class 2 5A Gases.  
· Label 2.2

· IMDG, IATA



· Class 2.2  
· Label 2.2

· 14.4 Packing group

· ADR, IMDG, IATA Not classified as hazardous for transport

· 14.5 Environmental hazards:

· Marine pollutant: No

· 14.6 Special precautions for user

· Danger code (Kemler): Warning: Gases.  
· EMS Number: -  
· Stowage Code F-D,S-U  
SW1 Protected from sources of heat.  
SW22 For AEROSOLS with a maximum capacity of 1 litre:  
Category A. For AEROSOLS with a capacity above 1 litre:  
Category B. For WASTE AEROSOLS: Category C, Clear  
of living quarters.  
· Segregation Code SG69 For AEROSOLS with a maximum capacity of 1 litre:  
Segregation as for class 9. Stow "separated from" class 1  
except for division 1.4. For AEROSOLS with a capacity  
above 1 litre: Segregation as for the appropriate

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·	subdivision of class 2. For WASTE AEROSOLS: Segregation as for the appropriate subdivision of class 2.
· <b>14.7 Transport in bulk according to Annex II of Marpol and the IBC Code</b>	Not applicable.
· <b>Transport/Additional information:</b>	
· <b>ADR</b>	
· <b>Limited quantities (LQ)</b>	1L
· <b>Excepted quantities (EQ)</b>	Code: E0 Not permitted as Excepted Quantity
· <b>Transport category</b>	3
· <b>Tunnel restriction code</b>	E
· <b>IMDG</b>	
· <b>Limited quantities (LQ)</b>	1L
· <b>Excepted quantities (EQ)</b>	Code: E0 Not permitted as Excepted Quantity
· <b>UN "Model Regulation":</b>	UN 1950 AEROSOLS, 2.2

### SECTION 15: Regulatory information

- **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**  
not applicable
- **Directive 2012/18/EU**
- **Named dangerous substances - ANNEX I** None of the ingredients is listed.
- **REGULATION (EC) No 1907/2006 ANNEX XVII** Conditions of restriction: 3
- **National regulations:**
- **Other regulations, limitations and prohibitive regulations**  
Complies with Directive 2007/47/EC amending directive 90/385/EEC, directive 93/42/CEE and directive 98/8/EC  
ICPE Regulation :  
1510 : Covered warehouses, storage of materials, products or combustible substances
- **15.2 Chemical safety assessment:** A Chemical Safety Assessment has not been carried out.

### SECTION 16: Other information

This information is based on our present knowledge. However, this shall not constitute a guarantee for any specific product features and shall not establish a legally valid contractual relationship.

- **Relevant phrases**  
H281 Contains refrigerated gas; may cause cryogenic burns or injury.

· **Classification according to Regulation (EC) No 1272/2008**

Aerosols | Bridging principles

· **Abbreviations and acronyms:**

ADR: Accord européen sur le transport des marchandises dangereuses par Route (European Agreement concerning the International Carriage of Dangerous Goods by Road)  
IMDG: International Maritime Code for Dangerous Goods  
IATA: International Air Transport Association  
GHS: Globally Harmonised System of Classification and Labelling of Chemicals  
EINECS: European Inventory of Existing Commercial Chemical Substances  
ELINCS: European List of Notified Chemical Substances  
CAS: Chemical Abstracts Service (division of the American Chemical Society)  
PBT: Persistent, Bioaccumulative and Toxic

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*SVHC: Substances of Very High Concern*  
*vPvB: very Persistent and very Bioaccumulative*  
*Aerosol 3: Aerosols – Category 3*

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