

Safety data sheet
according to 1907/2006/EC, Article 31

Printing date 02.09.2014

Version number 1

Revision: 02.09.2014

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

- **1.1 Product identifier**
- **Trade name: Silence Throat Spray**
- **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:**
*Omega Pharma NV
Venecoweg, 26
B-9810 Nazareth
www.omega-pharma.be
T +32 (0)9 381 02 00
Fax : +32 9 381 02 20
Mail : info@omega-pharma.com*
- **1.4 Emergency telephone number:**
*France (ORFILA 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*

SECTION 2: Hazards identification

- **2.1 Classification of the substance or mixture**
- **Classification according to Regulation (EC) No 1272/2008 :**
H229 Pressurised container: May burst if heated.
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC : Not applicable.**
- **Information concerning particular hazards for human and environment:**
The product does not have to be labelled due to the calculation procedure of the "General Classification guideline for preparations of the EU" in the latest valid version.
- **Classification system:**
The classification is according to the latest editions of the EU-lists, and extended by company and literature data.
- **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 for transport*
- **Signal word** *Warning*
- **Hazard statements**
H229 Pressurised container: May burst if heated.
- **Precautionary statements**
*P251 Do not pierce or burn, even after use.
P210 Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking.
P410+P412 Protect from sunlight. Do not expose to temperatures exceeding 50 °C/122 °F.*
- **Additional information:**
Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50°C. Do not pierce or burn, even after use.
- **2.3 Other hazards**
- **Results of PBT and vPvB assessment**
- **PBT:** *Not applicable.*
- **vPvB:** *Not applicable.*

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SECTION 3: Composition/information on ingredients

- **3.2 Chemical characterization: Mixtures**
- **Description:** *Isotonique: 9‰*
- **Dangerous components:** *Not classified as hazardous for transport*
- **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.*

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- **Further information about storage conditions:**
Protect from heat and direct sunlight.
Protect from frost.
- **7.3 Specific end use(s) :** No further relevant information available.

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:**
As a basis for the production of this document, the most current valid lists were used.
- **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:**

Form:	Liquid
Colour:	Colourless
Odour:	Odourless
Odour threshold:	Not determined.
- **pH-value:** Not determined.
- **Change in condition**

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	Undetermined.
- **Flash point:** Not applicable.
- **Flammability (solid, gaseous):** Not applicable.
- **Ignition temperature:** Not applicable.
- **Decomposition temperature:** Not determined.
- **Self-igniting:** Product is not self igniting.
- **Danger of explosion:** Product does not present an explosion hazard.
- **Explosion limits:**

Lower:	Not determined.
Upper:	Not determined.

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· Vapour pressure:	<i>Not determined.</i>
· Density at 20 °C:	<i>1 g/cm³</i>
· Relative density :	<i>Not determined.</i>
· Vapour density :	<i>Not determined.</i>
· Evaporation rate :	<i>Not determined.</i>
· Solubility in / Miscibility with water:	<i>Fully miscible.</i>
· Segregation coefficient (n-octanol/water):	<i>Not determined.</i>
· Viscosity:	
Dynamic:	<i>Not determined.</i>
Kinematic:	<i>Not determined.</i>
· 9.2 Other information :	<i>No further relevant information available.</i>

SECTION 10: Stability and reactivity

- **10.1 Reactivity**
- **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:**
- **Primary irritant effect:**
- **On the skin:** *No irritant effect.*
- **On the eyes:** *No irritant effect.*
- **Sensitization:** *No sensitizing effects known.*
- **Additional toxicological information:**
The product is not subject to classification according to the calculation method of the General EU Classification Guidelines for Preparations as issued in the latest version.
When used and handled according to specifications, the product does not have any harmful effects to our experience and the information provided to us.

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.*

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- **12.5 Results of PBT and vPvB assessment**
- **PBT:** Not applicable.
- **vPvB:** Not applicable.
- **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	1950 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	Warning: Gases.
· Danger code (Kemler):	-
· EMS Number:	F-D,S-U
· 14.7 Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code	Not applicable.

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· **Transport/Additional information:**

· **ADR**

· **Limited quantities (LQ)**

IL

· **Excepted quantities (EQ)**

Code: E0

Not permitted as Excepted Quantity

· **Transport category**

3

· **Tunnel restriction code**

E

· **IMDG**

· **Limited quantities (LQ)**

IL

· **Excepted quantities (EQ)**

Code: E0

Not permitted as Excepted Quantity

· **UN "Model Regulation":**

UN1950, AEROSOLS, 2.2

SECTION 15: Regulatory information

· **15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture**
not applicable

· **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

· **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.

· **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 Harmonized 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)