

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

Printing date 03.09.2014




Version number 1

Revision: 03.09.2014

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

- **1.1 Product identifier**
- **Trade name:** Wartner Cryopharma 2nd Generation
- **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 :**  
 **GHS02**  
  
*Flam. Aerosol 1 H222-H229 Extremely flammable aerosol. Pressurised container: May burst if heated.*
- **Classification according to Directive 67/548/EEC or Directive 1999/45/EC :**  
 **F+; Extremely flammable**  
  
*R12: Extremely flammable.*
- **Information concerning particular hazards for human and environment:**  
*The product has to be labelled in the latest valid version according to the calculation procedure of the "General Classification guideline for preparations of the EU".*  
*Warning! Pressurized container.*
- **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**  
 **GHS02**
- **Signal word** *Danger*
- **Hazard statements**  
*H222-H229 Extremely flammable aerosol. Pressurised container: May burst if heated.*

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### · Precautionary statements

- P102 Keep out of reach of children.  
P251 Do not pierce or burn, even after use.  
P211 Do not spray on an open flame or other ignition source.  
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.  
Do not spray on a naked flame or any incandescent material. Keep away from sources of ignition - No smoking.

### · Labelling of packages where the contents do not exceed 125 ml

### · Hazard pictograms



GHS02

### · Signal word Danger

### · Hazard statements

H222-H229 Extremely flammable aerosol. Pressurised container: May burst if heated.

### · Precautionary statements

- P102 Keep out of reach of children.  
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### · 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 characterization: Mixtures

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

#### · Dangerous components:

CAS: 115-10-6 EINECS: 204-065-8 Index number: 603-019-00-8 RTECS: PM 4780000 Reg.nr.: 01-2119472128-37	dimethyl ether	 F+ R12  Flam. Gas 1, H220; Press. Gas, H280	10-25%
CAS: 74-98-6 EINECS: 200-827-9 Index number: 601-003-00-5 RTECS: TX 2275000	propane	 F+ R12  Flam. Gas 1, H220; Press. Gas, H280	2.5-10%

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

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### SECTION 4: First aid measures

- **4.1 Description of first aid measures**
- **After excessive inhalation:** Supply fresh air; consult a doctor in case of complaints.
- **After skin contact:** Generally the product does not irritate the skin.
- **After eye contact:** Rinse opened eye for several minutes under running water.
- **After swallowing:** If symptoms persist consult a doctor.
- **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:** CO<sub>2</sub>, sand, extinguishing powder. Do not use water.
- **For safety reasons unsuitable extinguishing agents:** Water with full jet
- **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 :**  
Wear protective equipment. Keep unprotected persons away.
- **6.2 Environmental precautions:** Do not allow to enter sewers/ surface or ground water.
- **6.3 Methods and material for containment and cleaning up:**  
Ensure adequate ventilation.  
Do not flush with water or aqueous cleansing agents
- **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 :**  
Keep receptacles tightly sealed.  
Keep away from heat and direct sunlight.  
Open and handle receptacle with care.
- **Information about fire - and explosion protection:**



Keep ignition sources away - Do not smoke.

Protect against electrostatic charges.

Pressurized container: protect from sunlight and do not expose to temperatures exceeding 50 °C, i.e. electric lights. Do not pierce or burn, even after use.

Do not spray onto a naked flame or any incandescent material.

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- **7.2 Conditions for safe storage, including any incompatibilities**
- **Storage:**
- **Requirements to be met by storerooms and receptacles:**  
Store in a cool location.  
Observe official regulations on storing packagings with pressurized containers.
- **Information about storage in one common storage facility:** Not required.
- **Further information about storage conditions:**  
Keep container tightly sealed.  
Do not seal receptacle gas tight.  
Store in cool, dry conditions in well sealed receptacles.  
Protect from heat and direct sunlight.
- **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:**

##### **115-10-6 dimethyl ether (10-25%)**

WEL (Great Britain)	Short-term value: 958 mg/m <sup>3</sup> , 500 ppm Long-term value: 766 mg/m <sup>3</sup> , 400 ppm
IOELV (EU)	Long-term value: 1920 mg/m <sup>3</sup> , 1000 ppm
MAK (Switzerland)	Long-term value: 1910 mg/m <sup>3</sup> , 1000 ppm

##### **74-98-6 propane (2.5-10%)**

MAK (Switzerland)	Short-term value: 7200 mg/m <sup>3</sup> , 4000 ppm Long-term value: 1800 mg/m <sup>3</sup> , 1000 ppm
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- **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:** Wash hands before breaks and at the end of work.
- **Respiratory protection:**  
Not required.  
Use suitable respiratory protective device in case of insufficient ventilation.
- **Protection of hands:** Not required.
- **Gloves material :**  
The selection of suitable gloves does not only depend on the material, but also on further marks of quality which may vary from manufacturer to manufacturer. As the product is a preparation of several substances, the resistance of the glove material can not be calculated in advance and has therefore to be checked before use.
- **Eye protection:**



Tightly sealed goggles

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### SECTION 9: Physical and chemical properties

#### · 9.1 Information on basic physical and chemical properties

##### · General Information

##### · Appearance:

Form:	Aerosol
Colour:	According to product specification
Odour:	Characteristic
Odour threshold:	Not determined.

· pH-value: Not determined.

##### · Change in condition

Melting point/Melting range:	Undetermined.
Boiling point/Boiling range:	-44 °C

· Flash point: -97 °C

· Flammability (solid, gaseous): Not applicable.

· Ignition temperature: 235 °C

· Decomposition temperature: Not determined.

· Self-igniting: Product is not self igniting.

· Danger of explosion: Not determined.

##### · Explosion limits:

Lower:	3.0 Vol %
Upper:	18.6 Vol %

· Vapour pressure at 20 °C: 5200 hPa

· Density: Not determined.

· Relative density : Not determined.

· Vapour density : Not determined.

· Evaporation rate : Not applicable.

· Solubility in / Miscibility with water:

Not miscible or difficult to mix.

· Segregation coefficient (n-octanol/water): Not determined.

##### · Viscosity:

Dynamic: Not determined.

Kinematic: Not determined.

· 9.2 Other information : No further relevant information available.

### 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.

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- **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.

### 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:**  
Water hazard class 1 (German Regulation) (Self-assessment): slightly hazardous for water.  
Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.
- **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 :**



Must not be disposed of together with household garbage. Do not allow product to reach sewage system.

- **Uncleaned packaging:**
- **Recommendation:** Disposal must be made according to official regulations.

### SECTION 14: Transport information

- |   |  |
|---|--|
| <ul style="list-style-type: none"> <li>· <b>14.1 UN-Number</b></li> <li>· <b>ADR, IMDG, IATA</b></li> </ul>   | UN1950   |
| <ul style="list-style-type: none"> <li>· <b>14.2 UN proper shipping name</b></li> <li>· <b>ADR</b></li> <li>· <b>IMDG</b></li> <li>· <b>IATA</b></li> </ul> | 1950 AEROSOLS<br>AEROSOLS<br>AEROSOLS, flammable |

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### · 14.3 Transport hazard class(es)

#### · ADR



- Class 2 5F Gases.
- Label 2.1

#### · IMDG, IATA



- Class 2.1
- Label 2.1

### · 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.

#### · Transport/Additional information:

#### · ADR

- Limited quantities (LQ) 1L
- Excepted quantities (EQ) Code: E0
- Not permitted as Excepted Quantity
- Transport category 2
- Tunnel restriction code D

#### · IMDG

- Limited quantities (LQ) 1L
- Excepted quantities (EQ) Code: E0
- Not permitted as Excepted Quantity

- UN "Model Regulation": UN1950, AEROSOLS, 2.1

## SECTION 15: Regulatory information

- 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture  
No further relevant information available.

- 15.2 Chemical safety assessment: A Chemical Safety Assessment has not been carried out.

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**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**

H220 Extremely flammable gas.

H280 Contains gas under pressure; may explode if heated.

R12 Extremely flammable.

· **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)

Flam. Gas 1: Flammable gases, Hazard Category 1

Flam. Aerosol 1: Flammable aerosols, Hazard Category 1

Press. Gas: Gases under pressure: Compressed gas