

# SAFETY DATA SHEET

(Regulation EC No.1907/2006 amended – Annex II)



**COMPANY:** LABORATOIRES URGO  
**BRAND:** URGO  
**PRODUCT NAME:** URGOTUL Neutre  
**Creation date:** oct. 2011  
**Version:** 1.1

**SDS n°:** FDS046  
**Print date:** 15/09/2017  
**Update :** 01/09/2016

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

### 1.1. PRODUCT IDENTIFIER

**Product Name:** URGOTUL Neutre  
**Type of product:** Mixture.  
Medical Device.

### 1.2. RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

**Identified uses:** Patient use.  
**Uses advised against:** See contra-indications in the patient leaflet

### 1.3. DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

**Manufacturer /Supplier:** LABORATOIRES URGO.  
**Address:** 42 rue de Longvic  
21300 Chenôve.  
**Tel:** +33.(0)3.80.54.50.00.  
**Fax:** +33.(0)3.80.44.74.52.  
**Email:** [info@laboratoiresurgo.fr](mailto:info@laboratoiresurgo.fr)  
**Website :** [www.urgo.fr](http://www.urgo.fr)  
**Contact person:** Mister Gilles Guérin.

### 1.4. EMERGENCY TELEPHONE NUMBER

**Emergency phone number:** INRS / ORFILA: +33.(0)1.45.42.59.59

## SECTION 2. HAZARDS IDENTIFICATION

### 2.1. CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

The classification according to CLP regulation is not applicable to the finished product for the health professionals in its commercial form according to the CLP regulation CE n°1272/2008, first article (this product is part of human drugs and medical invasive devices or is used in direct physical contact with the human body).

The Safety Data Sheet is not required according to the REACH regulation, article number 31 c).

#### **Classification according to Regulation EC No.1272/2008 (CLP):**

The product is not classified for its hazard properties to human health and / or environment.

Full text of hazard categories and H phrases is included in section 16.  
Procedure used for determining classification is included in section 16.

### 2.2. LABEL ELEMENTS

#### **2.2.1. Labelling according to Regulation EC No.1272/2008 (CLP):**

**Pictograms:** --  
**Signal word:** --  
**Hazard statements:** --  
**Additional hazard statements:** --  
**Precautionary statements:** --  
**Additional precautionary statements:** --  
**Other information:** --

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## 2.3. OTHER HAZARDS

**PBT/vPvB Properties (Annex XIII):** The product has not been evaluated for its PBT/vPvB properties.  
**Ingredients submitted to authorization (Annex XIV):** Not applicable.  
**Others:** No data available.

## SECTION 3. COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1. SUBSTANCES

Not applicable.

### 3.2. MIXTURES

#### 3.2.1. Components / impurities presenting a health or environmental hazard:

Component	identifier	Mass %	Classification
Mineral oil	CAS : 8042-47-5	0-40 %	H304
Alcools, C12-14-secondaires, éthoxylés	CAS : 84133-50-6	<1%	H315, H319, H400, H411

Full text of hazard categories and H phrases is included in section 16.

#### 3.2.2. Components / impurities presenting occupational TLV / TWA:

Component	identifier	Mass %	classification
Isopropanol	CAS : 67-63-0	<1%	H225, H336, H319

Full text of hazard categories and H phrases is included in section 16.

#### 3.2.3. Components / impurities classified PBT/vPvB and/or listed in the Candidate List:

Not applicable.

## SECTION 4. FIRST AID MEASURES

### 4.1. DESCRIPTION OF FIRST AID MEASURES

**General advice:** In general, in case of doubt or if symptoms persist, always call a doctor.  
Never give anything by mouth to an unconscious person.

**Inhalation:** Remove victim immediately from source of exposure.  
Supply fresh air-  
Consult a doctor if symptoms persist.

**Skin contact:** Remove contaminated clothing and wash with soap and water.  
Consult a doctor if discomfort caused by repeated exposure persists.

**Eye contact:** Rinse immediately with plenty of water for 15 minutes maximum.  
Remove contact lenses and open the eye.  
Consult a doctor if symptoms persist.

**Ingestion:** Rinse mouth immediately and drink plenty of water.  
Do not induce vomiting.  
Provide rest, warmth and fresh air.  
Consult a doctor if symptoms persist.

**Personal protective equipment for rescue workers:** See section 8.

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## 4.2. MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED

**Inhalation:** No data available.  
**Skin contact:** This speciality contains terpene derivatives that can induce, if overdosed, neurological accidents like convulsions for infants and child.  
**Eye contact:** No data available.  
**Ingestion:** No data available.

## 4.3. INDICATION OF ANY IMMEDIATE MEDICAL ATTENTION AND SPECIAL TREATMENT NEEDED

No recommendation, but first aid may be required in case of accidental inhalation or ingestion.  
If in doubt: seek medical attention.

## SECTION 5. FIREFIGHTING MEASURES

### 5.1. EXTINGUISHING MEDIA

**Suitable extinguishing media:** In case of fire, use carbon dioxide, powder or water spray.  
Adapt the fire extinction measures to the environment.  
**Unsuitable extinguishing media:** --

### 5.2. SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE

**Hazardous combustion products:** Fumes emitted by thermal decomposition may be toxic: carbon monoxide, carbon dioxides.  
**Particular risk in case of fire or explosion:** In case of fire and / or explosion do not breathe fumes.

### 5.3. ADVICE FOR FIREFIGHTERS

**Flammable class:** Non-flammable.  
**Protection against fire:** Wear self-contained breathing apparatus and full protective clothing.  
**Special procedures:** Do not allow contaminated extinguishing water in sewers or waterways.  
Fire residues and contaminated firefighting water must be disposed of according to local regulations.  
**Surrounding fires:** No data available.

## SECTION 6. ACCIDENTAL RELEASE MEASURES

### 6.1. PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY PROCEDURES

#### 6.1.1. For non-emergency personnel:

**Protective equipment:** See section 8.  
**Emergency procedure:** No data available.

#### 6.1.2. For emergency responders:

Follow precautions for safe handling described in this safety data sheet.  
Ensure adequate ventilation.  
Wear protective equipment. Keep unprotected persons away.

### 6.2. ENVIRONMENTAL PRECAUTIONS

Collect and dispose by appropriate waste disposal agent.  
Do not wash away into sewer or in the environment.  
In case of seepage into water course or sewage system inform responsible authorities.

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## 6.3. METHODS AND MATERIAL FOR CONTAINMENT AND CLEANING UP

### 6.3.1. Appropriate means for spill containment:

No data available.

### 6.3.2. Appropriate means of the clean-up:

Ventilate the area.

Do not touch or walk through spilled material.

Absorb with inert, damp non-combustible material, then flush area with water.

Collect spillage into a clean suitable container, seal securely and deliver for disposal according to local regulations.

### 6.3.3. Others information:

No data available.

## 6.4. REFERENCE TO OTHER SECTIONS

See sections 8 and 13 for more information.

## SECTION 7. HANDLING AND STORAGE

### 7.1. PRECAUTIONS FOR SAFE HANDLING

**Protection measures:** Avoid unnecessary exposure.

**Measures to prevent a fire:** Keep away from ignition sources (heat, sparks or open flames).  
Ensure adequate ventilation.  
Do not pierce the container even after use.  
Do not smoke.

**Measures to prevent aerosol generation and dust:**

**Measures to protect environment:** Do not wash away into sewer or in the environment.

In case of seepage into water course or sewage system inform responsible authorities.

**General advice on hygiene of workers:**

Wash hands and any other exposed area with soap and water before eating, drinking, smoking and when leaving work.

For immediate action, train the staff on how to handle fire extinguishers.

### 7.2. CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES

**Technical measures and storage conditions:** Store in a cool, dry, well ventilated place, away from direct sunlight and ignition sources.  
Store plat.

**Packaging materials:** No data available.

**Requirements for storage and containers:** Ensure retention of firefighting water.

**Storage class:** Store in accordance with the incompatibility rules, keep away from corrosive products.

### 7.3. SPECIFIC END USE(S)

The identified uses for this product are listed in Section 1.2.

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## SECTION 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1. CONTROL PARAMETERS

#### 8.1.1. Occupational exposure (France: country providing the SDS):

Component	identifier	VLEP	DNEL / DMEL
Isopropanol	CAS: 67-63-0	980mg/m3	Conso ? Pro ?

#### 8.1.2. Environmental exposure:

Component Name	CAS No	PNEC
Isopropanol	CAS: 67-63-0	Freshwater: 140.9 mg/L Seawater: 140.9 mg/L Intermittent release of water: 140.9 mg/L Freshwater sediment: 552 mg/kg Seawater sediment: 552 mg/kg Soil: 28 mg/kg STP: 2251 mg/L

Source: Supplier data

### 8.2. EXPOSURE CONTROLS

#### 8.2.1. Appropriate engineering controls:

**Measures related to substance/mixture:** --  
**Structural measures:** Maintain appropriate local and global exhaust ventilation.  
**Organisational measures:** Think about analysing risks (prevention plan, work permits, etc.).  
**Technical measures:** No data available.

#### 8.2.2. Personal protective measures:

Promote collective protection measures in relation to personal protective measures. Collective protection measures are indicated for a professional use (isolated personal use not concerned).

**Eye / Face protection:** --  
**Hand protection:** --  
**Body protection:** Not ordinarily required beyond standard work clothes.  
**Respiratory protection:** If ventilation is insufficient, suitable respiratory protection must be provided.  
**Thermal hazards:** No data available.  
**Hygiene measures:** Use usual precautionary measures for handling chemicals.  
Wash hands after manipulation.  
Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed.

#### 8.2.3. Environmental protection measures:

**Measures related to substance/mixture:** Do not wash away into sewer or in the environment.  
**Instruction measures:** No data available.  
**Organisational measures:** No data available.  
**Technical measures:** No data available.

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## SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

### 9.1. INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES

*Physical state:* solid  
*Colour:* flesh  
*Odour:* --  
*Odour Threshold:* No data available.  
*pH:* No data available.  
*Melting / freezing point:* No data available.  
*Initial boiling point and boiling range:* No data available.  
*Flash point:* >200°C  
*Evaporation rate:* No data available.  
*Flammability (solid, gas):* No data available.  
*Upper / lower flammability limits:* No data available.  
*Upper / lower explosive limits:* No data available.  
*Vapour pressure:* No data available.  
*Vapour density:* No data available.  
*Relative density:* No data available.  
*Solubility:* No data available.  
*n-octanol/water partition coefficient:* No data available.  
*Auto-ignition temperature:* No data available.  
*Decomposition temperature:* No data available.  
*Viscosity:* No data available.  
*Explosive Properties:* No data available.  
*Oxidizing properties:* No data available.

## SECTION 10. STABILITY AND REACTIVITY

### 10.1. REACTIVITY

No reactivity hazards known.

### 10.2. CHEMICAL STABILITY

The product is stable under normal conditions of use.

### 10.3. POSSIBILITY OF HAZARDOUS REACTIONS

Under normal conditions of storage and use, hazardous reactions will not occur.

### 10.4. CONDITIONS TO AVOID

Temperature elevation.  
Avoid all possible sources of ignition (spark, heat or flame).

### 10.5. INCOMPATIBLE MATERIALS

None.

### 10.6. HAZARDOUS DECOMPOSITION PRODUCTS

Carbon monoxide, carbon dioxide.

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## SECTION 11. TOXICOLOGICAL INFORMATION

### 11.1. INFORMATION ON TOXICOLOGICAL EFFECTS

#### 11.1.1. Information on the substance:

Not applicable.

#### 11.1.2. Information on the mixture:

No data is available on the finished product.

According to available data on the components and according to the rule of additivity:

<b>Acute Toxicity:</b>	<u>According to the data on the components:</u> Not classified for acute toxicity. (Additivity rule).
<b>Skin corrosion/irritation:</b>	<u>According to the data on the components:</u> Not classified as skin irritating. (Additivity rule).
<b>Serious eye damage / eye irritation:</b>	<u>According to the data on the components:</u> Not classified as eye irritating. (Additivity rule).
<b>Respiratory or skin sensitization:</b>	<u>According to the data on the components:</u> Not classified as skin sensitizing. (Additivity rule).
<b>Germ Cell Mutagenicity:</b>	<u>According to the data on the components:</u> Not classified as mutagen (Additivity rule).
<b>Carcinogenicity:</b>	<u>According to the data on the components:</u> Not classified as carcinogen (Additivity rule).
<b>Reproductive Toxicity:</b>	<u>According to the data on the components:</u> Not classified as reproductive toxic (Additivity rule).
<b>Specific target organ toxicity (STOT) – single exposure:</b>	<u>According to the data on the components:</u> Not classified as specific organ toxic, single exposure. (Additivity rule).
<b>Specific target organ toxicity (STOT) – repeated exposure:</b>	<u>According to the data on the components:</u> Not classified as specific organ toxic, repeated exposure. (Additivity rule).
<b>Aspiration hazard:</b>	<u>According to the data on the components:</u> Not classified as aspiration hazard. (Additivity rule).

#### 11.1.3. Information on likely routes of exposure:

Exposure may occur by oral and dermal routes under normal use.

#### 11.1.4. Symptoms related to the physical, chemical and toxicological characteristics:

See section 4.2.

#### 11.1.5. Delayed, immediate and chronic effects of exposure to short or long term:

See section 4.2.

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## 11.1.6. Interactive effects:

No data available.

## 11.1.7. Absence of specific data:

No available data on similar mixtures.

## 11.1.8. Information on mixtures and information on substances:

No data available.

## 11.1.9. Other information:

No additional data available.

## **SECTION 12. ECOLOGICAL INFORMATION**

No data is available on finished product.

According to available data on the components and according to the rule of additivity, the product is considered harmful to aquatic life with long lasting effects (EC Regulation N°. 1272/2008 as amended).

### **12.1. TOXICITY**

Insufficient data is available to determine the classification of the product.

**Acute toxicity:** Insufficient data is available to determine the classification of the product.

Fishes: --

Crustaceans: --

Algae / Aquatic plant: --

Other organisms: --

**Chronic toxicity:** Insufficient data is available to determine the classification of the product.

### **12.2. PERSISTENCE AND DEGRADABILITY**

Insufficient data is available to determine the classification of the product.

### **12.3. BIOACCUMULATIVE POTENTIAL**

Insufficient data is available to determine the classification of the product.

### **12.4. MOBILITY IN SOIL**

Insufficient data is available to determine the classification of the product.

### **12.5. RESULTS OF PBT AND vPvB ASSESSMENT**

The product has not been evaluated for its PBT/vPvB properties (Regulation EC No. 1907/2006 – Annex XIII).

### **12.6. OTHER ADVERSE EFFECTS**

No additional data available.

## **SECTION 13. DISPOSAL CONSIDERATIONS**

### **13.1. WASTE TREATMENT METHODS**

Dispose of according to local regulations.

Contaminated containers must not be treated as household wastes: It may contain hazardous residues.

The contaminated and/or soiled packaging should be disposed of via a licensed waste disposal contractor.



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## 13.1.1. Disposal of the product / packaging:

**Hazard classification:** Not classified.  
Do not wash away contaminated water into environment

## 13.1.2. Relevant information about the waste treatment:

No additional data available.

## 13.1.3. Relevant information about the disposal of sewage:

No additional data available.

## 13.1.4. Other recommendations for the disposal:

No additional data available.

## **SECTION 14. TRANSPORT INFORMATION**

According to the requirements of ADR / RID / ADNR / IMDG / ICAO / IATA.

The product is not classified.

### **14.1. UN NUMBER**

--

### **14.2. UN PROPER SHIPPING NAME**

--

### **14.3. TRANSPORT HAZARD CLASS(ES)**

**Hazard class:** --

**Hazard label:** --

### **14.4. PACKING GROUP**

None.

### **14.5. ENVIRONMENTAL HAZARDS**

None.

### **14.6. SPECIAL PRECAUTIONS FOR USER**

--

### **14.7. Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code**

Not applicable.

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## SECTION 15. REGULATORY INFORMATION

### 15.1. SAFETY, HEALTH AND ENVIRONMENTAL REGULATIONS / LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE

#### 15.1.1. European regulations:

**Regulation EC No. 1907/2006 (REACH) amended:** The mixture in its finished state product for consumer use is exempt from Title IV. "Inside information in the supply chain."  
However, the components of the mixture are affected by all the provisions of the Regulation:  
- All components subject to registration have been pre-registered.  
- No component of the mixture is subject to authorization (Annex XIV) or to restriction (annexes XVII).  
- No component is included in the Candidate List for authorization.

**Regulation EC No 1272/2008 (CLP) amended:** The mixture in its finished state product for consumer use is not concerned by the regulation related to the classification, labelling and packaging of substances and mixtures:  
- Not subject to hazard classification.  
- Not subject to labelling of dangerous properties.  
- Not subject to specific packaging.

**Regulation EC No 2004/42 amended:** VOC content: no data available.

#### 15.1.2. National regulations (France):

**Occupational diseases:** Not applicable.

**Classification according to French ICPE regulation:** Not applicable

**Other regulations:** This product complies with Decree No. 2006-352 of 20/03/2006 related to the placing of food supplements on the French market and transposing Directive 2002/46/EC.

This product is part of human drugs and medical invasive devices or is used in direct physical contact with the human body, the safety data Sheet is not required according to the REACH regulation article number 31, c)

### 15.2. CHEMICAL SAFETY ASSESSMENT

The product has not been evaluated.

## SECTION 16. OTHER INFORMATION

### 16.1. PROCEDURE USED TO DERIVE THE CLASSIFICATION ACCORDING TO REGULATION EC No. 1272/2008 (CLP):

Classification	Justification
Not classified	Additivity rule

### 16.2. FULL TEXT OF HAZARD CATEGORIES AND THE R AND H SHORT PHRASES CARRIED FORWARD ON THE SECTION 2 AND 3

**Full text of hazard categories:** Flammable liquids 2.  
Aspiration toxicity 1.  
Skin irritant 2.  
Serious eye irritation 2.  
Serious eye damage 1.  
STOT SE 3.  
Aquatic acute 1.

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Aquatic chronic 2

**Full text of H and P phrases:**

- H225: Highly flammable liquid and vapour.
- H304: May be fatal if swallowed and enters airways.
- H315: Causes skin irritation.
- H319: Causes serious eye irritation
- H336: May cause drowsiness or dizziness.
- H400: Very toxic to aquatic life.
- H411: Toxic to aquatic life with long lasting effects.

## 16.3. HISTORICAL OF CHANGES TO THE SAFETY DATA SHEET

<b>Date:</b>	<b>Subject:</b>	<b>Version:</b>
October 2011	SDS creation.	1.0
September 2016	Update	1.1

This sheet complements the technical sheets but does not replace them. The information contained within is based on our state of knowledge to the product, on the date indicated. These are given in good faith. Moreover, the user's attention is drawn to the possible risks incurred when a product is used for purposes other than those for which it was designed. It does in any case exonerate the user from knowing and applying all the regulations governing his activity. He will be solely responsible of the precautions related to the use he makes of the product. All regulatory prescriptions mentioned is to help the user to fulfil his obligations. This list cannot be considered exhaustive. The recipient must ensure that other obligations do not incumbent on him because of texts other than those mentioned.