

## ENGLISH

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

#### 1.1 Product identifiers

Product name: Enterosystem 18R  
Product Number: 71618-79618

#### 1.2 Identified uses of the relevant substance or mixture and uses advised against

Identified uses relevant: Professional uses, Health services, scientific research and development

#### 1.3 Details of the supplier of the safety data sheet

Manufacturer/Supplier: Liofilchem®  
Address: Via Scozia, zona industriale, 64026 - Roseto degli Abruzzi (TE)  
Telephone number: 085/8930745  
Fax number: 085/8930330  
E-mail address: liofilchem@liofilchem.net

#### 1.4 Emergency telephone number

+39 02-66101029 (Centro Antiveneni Niguarda Cà Granda - Milano).

This is a summary MSDS for a kit, for the full MSDS for each of the components refer to section 16.

### 2. HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance or mixture

This product does not meet the criteria for classification in any hazard class in accordance to Regulation (EC) No. 1272/2008, concerning the classification, labelling and packaging of substances and mixtures.

#### 2.2 Label elements

The product does not need to be labeled in accordance with EC directives or respective national laws.

#### 2.3 Other hazards - none

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

Refer to component MSDS

### 4. FIRST AID MEASURES

Refer to component MSDS

### 5. FIRE-FIGHTING MEASURES

Refer to component MSDS

### 6. ACCIDENTAL RELEASE MEASURES

Refer to component MSDS

### 7. HANDLING AND STORAGE

#### 7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid inhalation of vapour or mist. Do not eat, drink or smoking in work areas, wash hands after use; and remove contaminated clothing and protective equipment before entering areas where you eat.

#### 7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.  
Recommended storage temperature, see the product label.

#### 7.3 Specific end uses

Apart from the uses described in section 1.2 are not covered other specific uses.

### 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Refer to component MSDS

### 9. PHYSICAL AND CHEMICAL PROPERTIES

Refer to component MSDS

### 10. STABILITY AND REACTIVITY

Refer to component MSDS

## 11. TOXICOLOGICAL INFORMATION

Refer to component MSDS

## 12. ECOLOGICAL INFORMATION

Refer to component MSDS

## 13. DISPOSAL CONSIDERATIONS

Refer to component MSDS

## 14. INFORMAZIONI SUL TRASPORTO

### 14.1 UN number

ADR/RID: -                      IMDG: -                      IATA: -

Refer to component MSDS

### 14.2 UN proper shipping name

ADR/RID: Refer to component MSDS

IMDG: Refer to component MSDS

IATA: Refer to component MSDS

### 14.3 Transport hazard class(es)

ADR/RID: -                      IMDG: -                      IATA: -

Refer to component MSDS

### 14.4 Packaging group

ADR/RID: -                      IMDG: -                      IATA: -

Refer to component MSDS

### 14.5 Environmental hazards

ADR/RID: -                      IMDG: -                      IATA: -

Refer to component MSDS

### 14.6 Special precautions for user

no data available

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

no data available

## 15. REGULATORY INFORMATION

This safety datasheet complies with the requirements of European Parliament and of the Council Regulation (EC) No. 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) and Commission Regulation (EU) No. 453/2010 amending Commission Regulation (EC) No. 1907/2006.

### 15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture

The product is classified, coded and labeled in accordance with EU Regulation on Hazardous Materials.

### 15.2 Chemical Safety Assessment

This product has not been made a chemical safety assessment.

## 16. OTHER INFORMATION

### Kit Components:

|         |                        |               |
|---------|------------------------|---------------|
| \$71618 | Enterosystem 18R       | Not Dangerous |
| 20095   | Physiological Solution | Not Dangerous |

## Abbreviations and acronyms

ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road

CLP: Regulation concerning the classification, labelling and packaging of substances and mixtures, Regulation (EC) No. 1272/2008.

GHS: Globally Harmonized System of Classification and Labelling of Chemicals

IATA: International Air Transport Association

IMDG: International Maritime Code for Dangerous Goods

CL50: Middle lethal concentration of individuals in essay

DL50: The median lethal dose that causes death in 50% of individuals in essay

PBT: Persistent, bioaccumulative and toxic substance

REACH: Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), Regulation (EC) No. 1907/2006

RID: Regulations concerning the International Carriage of Dangerous Goods by Rail

vPvB: Very persistent and very bioaccumulative substance

## Training advice

The product must be used by qualified personnel. It is recommended to provide basic training with regard to safety and health at work to ensure proper handling of the product.

## Further information

This sheet replaces any previous edition.

The information in this document is based on the present state of our knowledge. The user must ensure the accuracy and completeness of such information in relation to the specific use intended.

Liofilchem® shall not be held liable for any damage resulting from handling or from contact with the above product. See [www.liofilchem.net](http://www.liofilchem.net) for additional terms and conditions of sale.

Previous date: 27.12.2012

Revision date: 01.06.2015

Revision Number: rev. 4

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#### 2.3 Other hazards - none

### 3. COMPOSITION / INFORMATION ON INGREDIENTS

#### 3.2 Mixtures

##### Hazardous substances

According to the applicable law is not necessary to declare any component

##### Additional information:

For the full text of H codes and R phrases mentioned in this section, see section 16

### 4. FIRST AID MEASURES

#### 4.1 Description of first aid measures

**General advice:** Consult a physician. Show this safety data sheet to the doctor in attendance.

**If inhaled:** If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

**In case of skin contact:** Wash off with soap and plenty of water. Consult a physician.

**In case of eye contact:** Flush eyes with water as a precaution.

**If swallowed:** Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

#### 4.2 Most important symptoms and effects, both acute and delayed

no data available

#### 4.3 Indication of any immediate medical attention and special treatment needed

no data available

### 5. FIRE-FIGHTING MEASURES

#### 5.1 Extinguishing media

Suitable extinguishing media: Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

#### 5.2 Special hazards arising from the substance or mixture

no data available

#### 5.3 Advice for firefighters

Wear self contained breathing apparatus for fire fighting if necessary.

### 6. ACCIDENTAL RELEASE MEASURES

#### 6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Ensure adequate ventilation.



## 10. STABILITY AND REACTIVITY

### 10.1 Reactivity

no data available

### 10.2 Chemical stability

Stable under recommended storage conditions

### 10.3 Possibility of hazardous reactions

no data available

### 10.4 Conditions to avoid

Exposure to direct solar light.

### 10.5 Incompatible materials

no data available

### 10.6 Hazardous decomposition products

No decomposition when used for the intended uses.

## 11. TOXICOLOGICAL INFORMATION

### 11.1 Information on toxicological effects

**Acute toxicity:** no data available

**Skin corrosion/irritation:** no data available

**Serious eye damage/eye irritation:** no data available

**Respiratory or skin sensitization:** no data available

**Germ cell mutagenicity:** no data available

**Carcinogenicity:** IARC: No component of this product present at levels greater than or equal to 0.1% is identified as probable, possible or confirmed human carcinogen by IARC.

**Reproductive toxicity:** no data available

**Specific target organ toxicity - single exposure:** no data available

**Specific target organ toxicity - repeated exposure:** no data available

**Aspiration hazard:** no data available

**Additional information:** RTECS: no data available

## 12. ECOLOGICAL INFORMATION

### 12.1 Toxicity

no data available

### 12.2 Persistence and degradability

no data available

### 12.3 Bioaccumulative potential

no data available

### 12.4 Mobility in soil

no data available

### 12.5 Results of PBT and vPvB assessment

This mixture contains no substances evaluated PBT or vPvB

### 12.6 Other adverse effects

no data available

## 13. DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

#### Product

Not be disposed of with household waste. Do not discharge into sewers.

The product must be specially treated adhering to official regulations administrative. Offer surplus and non-recyclable solutions to a licensed disposal company.

#### Contaminated packaging

Dispose of as unused product.



|                           |                               |
|---------------------------|-------------------------------|
| <b>Code Number (REF):</b> | <b>20079 – 20095 - 20195</b>  |
| <b>Description:</b>       | <b>Physiological Solution</b> |
| <b>Date of revision:</b>  | <b>Rev. 3 of 01.06.2015</b>   |

Liofilchem® certifies that the above-mentioned product is not classified hazardous and does not contains hazardous ingredients, substances with Community workplaces exposure limits or substances of very high concern above their disclosure limits according to the criteria described in Regulation (EC) No. 1272/2008. concerning the classification, labelling and packaging of substances and mixtures and its revisions. Consequently, a Material Safety Data Sheet is not provided for this product. (Regulation EC No. 1907/2006 - REACH).

The product must be used by qualified personnel.

Remind that the waste of the product must be carried out according to legislation in force and in conformity with local regulations

**Repetto Saverio**  
Regulatory Affairs  
(signature on file)

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