

(According to Regulation EC n° 1907/2006 and (UE) Regulation 878/2020) Revision: 5 / Revision Date: 17.04.2023

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 Antiveleni 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

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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

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(According to Regulation EC n° 1907/2006 and (UE) Regulation 878/2020) Revision: 5 / Revision Date: 17.04.2023

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.com. for additional terms and conditions of sale.

Previous date: 01.06.2015 Revision date: 17.04.2023 Revision Number: rev. 5

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(According to Regulation EC n° 1907/2006)

Revision: 4 / Revision Date: 01.06.2015

ENGLISH

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

1.1 Product identifiers

Product name: Enterosystem 18R

Product Number: \$71618

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 Antiveleni Niguarda Cà Granda - Milano).

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

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.

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(According to Regulation EC n° 1907/2006)

Revision: 4 / Revision Date: 01.06.2015

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains. Discharge into the environment must be avoided

6.3 Metodi e materiali per il contenimento e per la bonifica

Pick up and arrange disposal without creating dust. Sweep up and shovel. Keep in suitable, closed containers for disposal.

6.4 Reference to other sections

For information on safe handling, see Chapter 7.

For information on personal protection equipment see Chapter 8.

For disposal information see Chapter 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Do not eat, drink or smoke 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 Store in well closed original containers, keeping far from direct light.

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

8.1 Control parameters

Components with workplace control parameters

Contains no substances with occupational exposure limit value.

8.2 Exposure controls

Exposure controls

Handle in accordance with good hygiene and safety practice. Wash hands before breaks and at the end of workday.

No data available

Personal protective equipment

Eyes/Face Protection: It is advisable wear safety goggles

Skin protection: Handle with gloves

Body Protection: Use protective clothes in accordance with laboratory good practices.

Respiratory protection: It is advisable wear dust mask.

Environmental exposure control

For information relating to environmental precautions, see chapter 6.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance

Form Dryed powder
Color Multicolors wells
Odour

Odour Threshold No data available No data available Melting point/ freezing point No data available Initial boiling point and boiling range No data available Flash point No data available **Evaporation rate** No data available Flammability (solid, gas) not applicable Upper / lower flammability or explosive limits not applicable Vapour pressure No data available Vapour density No data available Relative density No data available

Water solubilitysolublePartition coefficient: n-octanol/waterNo data availableAutoignition temperatureNo data availableDecomposition temperatureNo data availableViscosityNo data availableExplosive propertiesNo data availableOxidizing propertiesNo data available

9.2 Other safety information

no data available

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Revision: 4 / Revision Date: 01.06.2015

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.

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(According to Regulation EC n° 1907/2006)

Revision: 4 / Revision Date: 01.06.2015

14. INFORMAZIONI SUL TRASPORTO

14.1 UN number

ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name

ADR/RID: Not dangerous goods IMDG: Not dangerous goods IATA: Not dangerous goods

14.3 Transport hazard class(es)

ADR/RID: - IMDG: - IATA: -

14.4 Packaging group

ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards

ADR/RID: no IMDG: no IATA: no

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

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vPvB: Very persistent and very bioaccumulative substance

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Previous date: 27.12.2012 Revision date: 01.06.2015 Revision Number: rev. 4

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Liofilchem[®] Non-Hazardous Product Statement

Code Number (REF): 20079 – 20095 - 20195

Description: Physiological Solution

Date of revision: Rev. 3 of 01.06.2015

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 and Regulation 2020/878).

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

Matteo Nallira
Regulatory Affairs
(signature on file)

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