

ENGLISH

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

1.1 Product identifiers

Product name: CultiControl pellets (Lyophilized microorganism preparations)
Product Number: 89XXX series

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, 64026 - Roseto Degli Abruzzi (TE), Italy
Telephone number: 085/8930745
Fax number: 085/8930330
E-mail address: liofilchem@liofilchem.com

1.4 Emergency telephone number

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

SECTION 2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008 [EU-GHS/CLP]

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.

CultiControl™ pellets contains a pure or mixed microorganism population. The microorganisms are classified as either Risk Group 1 or Risk Group 2 by the World Health Organization (WHO). These microorganisms may cause human infection, may pose a hazard to the laboratory personnel, but are unlikely to spread in the community. Exposure to these microorganisms in the laboratory rarely causes infection. Effective prevention and treatment is readily available.

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008 [CLP]

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

Hazard symbol(s)



Hazard statement(s)

Biohazard

Supplemental Hazard Statements none

2.3 Other hazards - none

SECTION 3. COMPOSITION / INFORMATION ON INGREDIENTS

3.2 Mixtures

Hazardous substances

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

The product presents Risk of infection

Additional Information:

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

SECTION 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: Avoid the production of aerosols. If inhalation occurs, move to an area of fresh air and seek medical advice.

In case of skin contact: Non-irritant. If skin contact occurs, immediately wash with an appropriate biocide solution.

In case of eye contact: Avoid contact with eyes. If contact occurs, rinse opened eye for 15 minutes under running water. Then consult a doctor.

If swallowed: Avoid hand to mouth contact. If ingested, immediately call a doctor.

4.2 Most important symptoms and effects, both acute and delayed

no data available

Melting point/ freezing point	not applicable
Initial boiling point and boiling range	not applicable
Flash point	Product is not self igniting
Evaporation rate	not applicable
Flammability (solid, gas)	not applicable
Upper / lower flammability or explosive limits	not applicable
Vapour pressure	not applicable
Vapour density	not applicable
Relative density	not applicable
Water solubility	soluble
Partition coefficient: n-octanol/water	not applicable
Autoignition temperature	not applicable
Decomposition temperature	not applicable
Viscosity	not applicable
Explosive properties	Product is not explosive
Oxidizing properties	not applicable

9.2 Other safety information

no data available

SECTION 10. STABILITY AND REACTIVITY**10.1 Reactivity**

no data available

10.2 Chemical stability

Stable in normal conditions

10.3 Possibility of hazardous reactions

No dangerous reactions known

10.4 Conditions to avoid

None if used according to specifications.

10.5 Incompatible materials

None

10.6 Hazardous decomposition products

No decomposition if used according to specifications.

SECTION 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**SECTION 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 Endocrine disrupting properties

The mixture does not contain components considered to have endocrine disrupting properties according to REACH Article 57(f) or Commission Delegated regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at levels of 0.1% or higher.

12.7 Other adverse effects

no data available

SECTION 13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product

The lyophilized microorganisms and subsequent growth of these microorganisms on culture media are considered to be biohazard material. Agencies and statutes regulate the disposal of all biohazard materials. Each laboratory must be aware of and comply with the proper disposal of biohazard materials.

Contaminated packaging

Dispose of as unused product.

SECTION 14. TRANSPORT INFORMATION

14.1 UN number

ADR/RID: UN 3373 IMDG: UN 3373 IATA: UN 3373

14.2 UN proper shipping name

ADR/RID: BIOLOGICAL SUBSTANCE, CATEGORY B

IMDG: BIOLOGICAL SUBSTANCE, CATEGORY B

IATA: BIOLOGICAL SUBSTANCE, CATEGORY B

14.3 Transport hazard class(es)

ADR/RID: 6.2 IMDG: 6.2 IATA: 6.2

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

SECTION 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.
- the requirements of Commission Regulation EU 2020/878

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.

SECTION 16. OTHER INFORMATION

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.

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