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

4.3 Indication of any immediate medical attention and special treatment needed

no data available

SECTION 5. FIRE- FIGHTING MEASURES

5.1 Extinguishing media
Suitable extinguishing media: no data available

5.2 Special hazards arising from the substance or mixture
no data available

5.3 Advice for firefighters
no data available

SECTION 6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Ensure adequate ventilation.

6.2 Environmental precautions
In case of accidental spillage, contain the spilled material and immediately notify nearby personnel of the incident.

6.3 Methods and materials for containment and cleaning

Decontaminate the spill by flooding and soaking the spilled material with a suitable disinfectant. Allow sufficient time for the biocide activity of the disinfectant. Clean the area and material using disposable towels. Materials used in cleanup should be treated as biohazard material.

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.

SECTION 7. HANDLING AND STORAGE

7.1 Precautions for safe handling
Ensure adequate microbiological equipment and facilities to receive process, maintain, store and dispose of biohazard material. Proper techniques must be employed to avoid exposure and contact with microorganism growth. The microbiology laboratory personnel using these devices must be trained experienced and demonstrate proficiency in processing, maintaining, storing and disposing of biohazard material.

7.2 Conditions for safe storage, including any incompatibilities
Store devices in their original sealed packaging according to temperature specifications on labeling.

7.3 Specific end uses
no data available

SECTION 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.

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.

SECTION 9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance	
Form	Dry material with vital microorganisms
Color	According to product specification
Odour	Odorless
Odour Threshold	No data available
pH	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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