



## Safety Data Sheet

According to Annex II to REACH - Regulation (EU) 2020/878

### SECTION 1. Identification of the substance/mixture and of the company/undertaking

#### 1.1. Product identifier

Code: **4240001**  
Product name: **BACILLUS CEREUS ANTIMICROBIC SUPPLEMENT**

#### 1.2. Relevant identified uses of the substance or mixture and uses advised against

Intended use: **Laboratory chemical. Reagent for microbiology.**

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

Name: **BIOLIFE ITALIANA S.R.L.**  
Full address: **Viale Monza, 272**  
District and Country: **20128 Milano (Milano)**  
**Italia**  
Tel.: **0039 02 252091**  
e-mail address of the competent person responsible for the Safety Data Sheet: **mktg@biolifeitaliana.it**

#### 1.4. Emergency telephone number

For urgent inquiries refer to: **NHS111 in England: 111**  
**NHS24 in Scotland: 111**  
**NHS Direct in Wales: 111 or 0845 4647**  
**In an emergency, if the patient has collapsed or is not breathing properly, call 999**

### SECTION 2. Hazards identification

#### 2.1. Classification of the substance or mixture

The product is not classified as hazardous pursuant to the provisions set forth in EC Regulation 1272/2008 (CLP). However, since the product contains hazardous substances in concentrations such as to be declared in section no. 3, it requires a safety data sheet with appropriate information, compliant to (EU) Regulation 2020/878.

Hazard classification and indication: --

#### 2.2. Label elements

Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements.

Hazard pictograms: --

Signal words: --

Hazard statements:  
**EUH210** Safety data sheet available on request.

Precautionary statements: --

#### 2.3. Other hazards

On the basis of available data, the product does not contain any PBT or vPvB in percentage  $\geq$  than 0,1%.

The product does not contain substances with endocrine disrupting properties in concentration  $\geq$  0.1%.



## SECTION 3. Composition/information on ingredients

### 3.2. Mixtures

Contains:

Identification	x = Conc. %	Classification (EC) 1272/2008 (CLP)
<b>POLYMXIN B SULFATE</b>		
INDEX	16,5 ≤ x < 18	<b>Acute Tox. 4 H302</b>
EC		<b>LD50 Oral: 790 mg/kg</b>
215-774-7		
CAS		
1405-20-5		

The full wording of hazard (H) phrases is given in section 16 of the sheet.

## SECTION 4. First aid measures

### 4.1. Description of first aid measures

No effects requiring implementation of special first aid measures are expected. The following information represents practical indications of correct behaviour in the event of contact with a chemical product, even if not hazardous.

In case of doubt or in the presence of symptoms contact a doctor and show him this document.

In case of more severe symptoms, ask for immediate medical aid.

EYES: Remove, if present, contact lenses if the situation allows you to do so easily. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. Get medical advice/attention.

SKIN: Take off contaminated clothing. Wash immediately and thoroughly with running water (and soap if possible). Get medical advice.

Avoid further contact with contaminated clothing.

INGESTION: Do not induce vomiting unless explicitly authorised by a doctor. Do not give anything by mouth to an unconscious person. Get medical advice/attention.

INHALATION: Remove victim to fresh air, away from the accident scene. Get medical advice/attention.

#### Rescuer protection

It is good practice for rescuers lending support to a person who has been exposed to a chemical substance or to a mixture to wear personal protective equipment. The nature of such protection depends on the hazard level of the substance or mixture, on the type of exposure and on the extent of the contamination. In the absence of other more specific indications, use of disposable gloves in the event of possible contact with body fluids is recommended. For the type of PPE suitable for the characteristics of the substance or mixture, see section 8.

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

Specific information on symptoms and effects caused by the product are unknown.

DELAYED EFFECTS: Based on the information currently available, there are no known cases of delayed effects following exposure to this product.

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

If symptoms occur, whether acute or delayed, consult a doctor.

#### Means to have available in the workplace for specific and immediate treatment

Running water for skin and eye wash.

## SECTION 5. Firefighting measures

### 5.1. Extinguishing media

#### SUITABLE EXTINGUISHING EQUIPMENT

The extinguishing equipment should be of the conventional kind: carbon dioxide, foam, powder and water spray.

#### UNSUITABLE EXTINGUISHING EQUIPMENT

None in particular.

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

#### HAZARDS CAUSED BY EXPOSURE IN THE EVENT OF FIRE

Do not breathe combustion products.

**SECTION 5. Firefighting measures** ... / >>**5.3. Advice for firefighters****GENERAL INFORMATION**

Use jets of water to cool the containers to prevent product decomposition and the development of substances potentially hazardous for health. Always wear full fire prevention gear. Collect extinguishing water to prevent it from draining into the sewer system. Dispose of contaminated water used for extinction and the remains of the fire according to applicable regulations.

**SPECIAL PROTECTIVE EQUIPMENT FOR FIRE-FIGHTERS**

Normal fire fighting clothing i.e. fire kit (BS EN 469), gloves (BS EN 659) and boots (HO specification A29 and A30) in combination with self-contained open circuit positive pressure compressed air breathing apparatus (BS EN 137).

**SECTION 6. Accidental release measures****6.1. Personal precautions, protective equipment and emergency procedures**

If there are no contraindications, spray powder with water to prevent the formation of dust.

Wear suitable protective equipment (including personal protective equipment referred to under Section 8 of the safety data sheet) to prevent any contamination of skin, eyes and personal clothing. These indications apply for both processing staff and those involved in emergency procedures.

**6.2. Environmental precautions**

The product must not penetrate into the sewer system or come into contact with surface water or ground water.

**6.3. Methods and material for containment and cleaning up**

Collect the leaked product and place it in containers for recovery or disposal. If there are no contraindications, use jets of water to eliminate product residues.

Make sure the leakage site is well aired. Evaluate the compatibility of the container to be used, by checking section 10. Contaminated material should be disposed of in compliance with the provisions set forth in point 13.

**6.4. Reference to other sections**

Any information on personal protection and disposal is given in sections 8 and 13.

**SECTION 7. Handling and storage****7.1. Precautions for safe handling**

Before handling the product, consult all the other sections of this material safety data sheet. Avoid leakage of the product into the environment. Do not eat, drink or smoke during use. Remove any contaminated clothes and personal protective equipment before entering places in which people eat.

**7.2. Conditions for safe storage, including any incompatibilities**

Store only in the original container. Store the containers sealed, in a well ventilated place, away from direct sunlight. Keep containers away from any incompatible materials, see section 10 for details.

**7.3. Specific end use(s)**

Information not available

**SECTION 8. Exposure controls/personal protection****8.1. Control parameters**

Information not available

**8.2. Exposure controls**

As the use of adequate technical equipment must always take priority over personal protective equipment, make sure that the workplace is well aired through effective local aspiration.

**HAND PROTECTION**

In the case of prolonged contact with the product, protect the hands with penetration-resistant work gloves (see standard EN 374).

Work glove material must be chosen according to the use process and the products that may form. Latex gloves may cause sensitivity reactions.

**SKIN PROTECTION**

Wear category I professional long-sleeved overalls and safety footwear (see Regulation 2016/425 and standard EN ISO 20344). Wash body with soap and water after removing protective clothing.

**SECTION 8. Exposure controls/personal protection ... / >>****EYE PROTECTION**

Wear airtight protective goggles (see standard EN ISO 16321).

**RESPIRATORY PROTECTION**

None required, unless indicated otherwise in the chemical risk assessment.

**ENVIRONMENTAL EXPOSURE CONTROLS**

The emissions generated by manufacturing processes, including those generated by ventilation equipment, should be checked to ensure compliance with environmental standards.

**SECTION 9. Physical and chemical properties****9.1. Information on basic physical and chemical properties**

Properties	Value	Information
Appearance	solid powder	
Colour	white	
Odour	not available	
Melting point / freezing point	not available	
Initial boiling point	not applicable	
Flammability	not available	
Lower explosive limit	not available	
Upper explosive limit	not available	
Flash point	not applicable	
Auto-ignition temperature	not available	
Decomposition temperature	not available	
pH	7,0 - 7,4	Remark:in the complete medium Temperature: 25 °C
Kinematic viscosity	not available	
Solubility	not available	
Partition coefficient: n-octanol/water	not available	
Vapour pressure	not available	
Density and/or relative density	not available	
Relative vapour density	not available	
Particle characteristics	not available	

**9.2. Other information****9.2.1. Information with regard to physical hazard classes**

Information not available

**9.2.2. Other safety characteristics**

Information not available

**SECTION 10. Stability and reactivity****10.1. Reactivity**

There are no particular risks of reaction with other substances in normal conditions of use.

**10.2. Chemical stability**

The product is stable in normal conditions of use and storage.

**10.3. Possibility of hazardous reactions**

No hazardous reactions are foreseeable in normal conditions of use and storage.

**10.4. Conditions to avoid**

None in particular. However the usual precautions used for chemical products should be respected.

**SECTION 10. Stability and reactivity** ... / >>**10.5. Incompatible materials**

Information not available

**10.6. Hazardous decomposition products**

Information not available

**SECTION 11. Toxicological information**

In the absence of experimental data for the product itself, health hazards are evaluated according to the properties of the substances it contains, using the criteria specified in the applicable regulation for classification.

It is therefore necessary to take into account the concentration of the individual hazardous substances indicated in section 3, to evaluate the toxicological effects of exposure to the product.

**11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008**Metabolism, toxicokinetics, mechanism of action and other information

Information not available

Information on likely routes of exposure

Information not available

Delayed and immediate effects as well as chronic effects from short and long-term exposure

Information not available

Interactive effects

Information not available

ACUTE TOXICITY

ATE (Inhalation) of the mixture:	Not classified (no significant component)
ATE (Oral) of the mixture:	>2000 mg/kg
ATE (Dermal) of the mixture:	Not classified (no significant component)

POLYMXIN B SULFATE  
LD50 (Oral):

790 mg/kg MOUSE

SKIN CORROSION / IRRITATION

Does not meet the classification criteria for this hazard class

SERIOUS EYE DAMAGE / IRRITATION

Does not meet the classification criteria for this hazard class

RESPIRATORY OR SKIN SENSITISATION

Does not meet the classification criteria for this hazard class

GERM CELL MUTAGENICITY

Does not meet the classification criteria for this hazard class

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

Does not meet the classification criteria for this hazard class

STOT - SINGLE EXPOSURE

**SECTION 11. Toxicological information ... / >>**

Does not meet the classification criteria for this hazard class

**STOT - REPEATED EXPOSURE**

Does not meet the classification criteria for this hazard class

**ASPIRATION HAZARD**

Does not meet the classification criteria for this hazard class

**11.2. Information on other hazards**

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with human health effects under evaluation.

**SECTION 12. Ecological information**

Use this product according to good working practices. Avoid littering. Inform the competent authorities, should the product reach waterways or contaminate soil or vegetation.

**12.1. Toxicity**

Information not available

**12.2. Persistence and degradability**

Information not available

**12.3. Bioaccumulative potential**

Information not available

**12.4. Mobility in soil**

Information not available

**12.5. Results of PBT and vPvB assessment**

On the basis of available data, the product does not contain any PBT or vPvB in percentage  $\geq$  than 0,1%.

**12.6. Endocrine disrupting properties**

Based on the available data, the product does not contain substances listed in the main European lists of potential or suspected endocrine disruptors with environmental effects under evaluation.

**12.7. Other adverse effects**

Information not available

**SECTION 13. Disposal considerations****13.1. Waste treatment methods**

Reuse, when possible. Neat product residues should be considered special non-hazardous waste. Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations. The management of waste arising from the use or dispersal of this product must be organised in accordance with occupational safety regulations. See section 8 for possible need for PPE.

**CONTAMINATED PACKAGING**

Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

**SECTION 14. Transport information**

The product is not dangerous under current provisions of the Code of International Carriage of Dangerous Goods by Road (ADR) and by Rail (RID), of the International Maritime Dangerous Goods Code (IMDG), and of the International Air Transport Association (IATA) regulations.

**SECTION 14. Transport information** ... / >>**14.1. UN number or ID number**

not applicable

**14.2. UN proper shipping name**

not applicable

**14.3. Transport hazard class(es)**

not applicable

**14.4. Packing group**

not applicable

**14.5. Environmental hazards**

not applicable

**14.6. Special precautions for user**

not applicable

**14.7. Maritime transport in bulk according to IMO instruments**

Information not relevant

**SECTION 15. Regulatory information****15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture**Seveso Category - Directive 2012/18/EU: NoneRestrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006  
NoneRegulation (EU) 2019/1148 - on the marketing and use of explosives precursors  
not applicableSubstances in Candidate List (Art. 59 REACH)  
On the basis of available data, the product does not contain any SVHC in percentage  $\geq$  than 0,1%.Substances subject to authorisation (Annex XIV REACH)  
NoneSubstances subject to exportation reporting pursuant to Regulation (EU) 649/2012:  
NoneSubstances subject to the Rotterdam Convention:  
NoneSubstances subject to the Stockholm Convention:  
NoneHealthcare controls  
Information not available**15.2. Chemical safety assessment**

A chemical safety assessment has not been performed for the preparation/for the substances indicated in section 3.

**SECTION 16. Other information**

Text of hazard (H) indications mentioned in section 2-3 of the sheet:

<b>Acute Tox. 4</b>	Acute toxicity, category 4
<b>H302</b>	Harmful if swallowed.
<b>EUH210</b>	Safety data sheet available on request.

**LEGEND:**

- ADR: European Agreement concerning the carriage of Dangerous goods by Road
- ATE: Acute Toxicity Estimate
- CAS: Chemical Abstract Service Number
- CE50: Effective concentration (required to induce a 50% effect)
- CE: Identifier in ESIS (European archive of existing substances)
- CLP: Regulation (EC) 1272/2008
- DNEL: Derived No Effect Level
- EmS: Emergency Schedule
- GHS: Globally Harmonized System of classification and labeling of chemicals
- IATA DGR: International Air Transport Association Dangerous Goods Regulation
- IC50: Immobilization Concentration 50%
- IMDG: International Maritime Code for dangerous goods
- IMO: International Maritime Organization
- INDEX: Identifier in Annex VI of CLP
- LC50: Lethal Concentration 50%
- LD50: Lethal dose 50%
- OEL: Occupational Exposure Level
- PBT: Persistent, bioaccumulative and toxic
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- PMT: Persistent, mobile and toxic
- PNEC: Predicted no effect concentration
- REACH: Regulation (EC) 1907/2006
- RID: Regulation concerning the international transport of dangerous goods by train
- TLV: Threshold Limit Value
- TLV CEILING: Concentration that should not be exceeded during any time of occupational exposure.
- TWA: Time-weighted average exposure limit
- TWA STEL: Short-term exposure limit
- VOC: Volatile organic Compounds
- vPvB: Very persistent and very bioaccumulative
- vPvM: Very persistent and very mobile
- WGK: Water hazard classes (German).

**GENERAL BIBLIOGRAPHY**

1. Regulation (EC) 1907/2006 (REACH) of the European Parliament
2. Regulation (EC) 1272/2008 (CLP) of the European Parliament
3. Regulation (EU) 2020/878 (II Annex of REACH Regulation)
4. Regulation (EC) 790/2009 (I Atp. CLP) of the European Parliament
5. Regulation (EU) 286/2011 (II Atp. CLP) of the European Parliament
6. Regulation (EU) 618/2012 (III Atp. CLP) of the European Parliament
7. Regulation (EU) 487/2013 (IV Atp. CLP) of the European Parliament
8. Regulation (EU) 944/2013 (V Atp. CLP) of the European Parliament
9. Regulation (EU) 605/2014 (VI Atp. CLP) of the European Parliament
10. Regulation (EU) 2015/1221 (VII Atp. CLP) of the European Parliament
11. Regulation (EU) 2016/918 (VIII Atp. CLP) of the European Parliament
12. Regulation (EU) 2016/1179 (IX Atp. CLP)
13. Regulation (EU) 2017/776 (X Atp. CLP)
14. Regulation (EU) 2018/669 (XI Atp. CLP)
15. Regulation (EU) 2019/521 (XII Atp. CLP)
16. Delegated Regulation (UE) 2018/1480 (XIII Atp. CLP)
17. Regulation (EU) 2019/1148
18. Delegated Regulation (UE) 2020/217 (XIV Atp. CLP)
19. Delegated Regulation (UE) 2020/1182 (XV Atp. CLP)
20. Delegated Regulation (UE) 2021/643 (XVI Atp. CLP)
21. Delegated Regulation (UE) 2021/849 (XVII Atp. CLP)
22. Delegated Regulation (UE) 2022/692 (XVIII Atp. CLP)
23. Delegated Regulation (UE) 2023/707
24. Delegated Regulation (UE) 2023/1434 (XIX Atp. CLP)



**SECTION 16. Other information ... / >>**

- 25. Delegated Regulation (UE) 2023/1435 (XX Atp. CLP)
- 26. Delegated Regulation (UE) 2024/197 (XXI Atp. CLP)

- The Merck Index. - 10th Edition
- Handling Chemical Safety
- INRS - Fiche Toxicologique (toxicological sheet)
- Patty - Industrial Hygiene and Toxicology
- N.I. Sax - Dangerous properties of Industrial Materials-7, 1989 Edition
- IFA GESTIS website
- ECHA website
- Database of SDS models for chemicals - Ministry of Health and ISS (Istituto Superiore di Sanità) - Italy

**Note for users:**

The information contained in the present sheet are based on our own knowledge on the date of the last version. Users must verify the suitability and thoroughness of provided information according to each specific use of the product.

This document must not be regarded as a guarantee on any specific product property.

The use of this product is not subject to our direct control; therefore, users must, under their own responsibility, comply with the current health and safety laws and regulations. The producer is relieved from any liability arising from improper uses.

Provide appointed staff with adequate training on how to use chemical products.

**CALCULATION METHODS FOR CLASSIFICATION**

Chemical and physical hazards: Product classification derives from criteria established by the CLP Regulation, Annex I, Part 2. The data for evaluation of chemical-physical properties are reported in section 9.

Health hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 3, unless determined otherwise in Section 11.

Environmental hazards: Product classification is based on calculation methods as per Annex I of CLP, Part 4, unless determined otherwise in Section 12.

**Changes to previous review:**

The following sections were modified:

04 / 09 / 13.