Safety Data Sheet

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

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

1.1. Product identifier

Code: **4240017**
Product name **PRESTON ANTIMICROBIC SUPPLEMENT**

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

Intended use **Laboratory chemical product. 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 **NHS111in England: 111**
NHS24in 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 classified as hazardous pursuant to the provisions set forth in (EC) Regulation 1272/2008 (CLP) (and subsequent amendments and supplements). The product thus requires a safety datasheet that complies with the provisions of (EU) Regulation 2020/878.
Any additional information concerning the risks for health and/or the environment are given in sections 11 and 12 of this sheet.

Hazard classification and indication:

Germ cell mutagenicity, category 2	H341	Suspected of causing genetic defects.
Reproductive toxicity, category 1A	H360	May damage fertility or the unborn child.
Acute toxicity, category 2	H300	Fatal if swallowed.
Skin irritation, category 2	H315	Causes skin irritation.
Hazardous to the aquatic environment, chronic toxicity, category 2	H411	Toxic to aquatic life with long lasting effects.

2.2. Label elements

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

Hazard pictograms:

Signal words: Danger

Hazard statements:

SECTION 2. Hazards identification ... / >>

H341	Suspected of causing genetic defects.
H360	May damage fertility or the unborn child.
H300	Fatal if swallowed.
H315	Causes skin irritation.
H411	Toxic to aquatic life with long lasting effects.
	Restricted to professional users.

Precautionary statements:

P201	Obtain special instructions before use.
P280	Wear protective gloves/ protective clothing / eye protection / face protection.
P308+P313	IF exposed or concerned: Get medical advice / attention.
P301+P310	IF SWALLOWED: Immediately call a POISON CENTER / doctor / . . .
P273	Avoid release to the environment.
P391	Collect spillage.

Contains: CYCLOHEXIMIDE
RIFAMPICIN

2.3. Other hazards

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

The product does not contain substances with endocrine disrupting properties in concentration ≥ 0.1%.

SECTION 3. Composition/information on ingredients

3.2. Mixtures

Contains:

Identification		x = Conc. %	Classification (EC) 1272/2008 (CLP)
CYCLOHEXIMIDE			
INDEX	*613-140-00-8*	66 ≤ x < 70	**Muta. 2 H341, Repr. 1A H360, Acute Tox. 2 H300, Skin Irrit. 2 H315, Aquatic Chronic 2 H411**
EC	*200-636-0*		**STA Oral: 5,001 mg/kg**
CAS	*66-81-9*		
RIFAMPICIN			
INDEX		6 ≤ x < 7	**Acute Tox. 4 H302, Eye Irrit. 2 H319, Skin Irrit. 2 H315, STOT SE 3 H335**
EC	*236-312-0*		**LD50 Oral: 1570 mg/kg**
CAS	*13292-46-1*		

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

EYES: Remove contact lenses, if present. Wash immediately with plenty of water for at least 15 minutes, opening the eyelids fully. If problem persists, seek medical advice.
SKIN: Remove contaminated clothing. Rinse skin with a shower immediately. Get medical advice/attention immediately. Wash contaminated clothing before using it again.
INHALATION: Remove to open air. If the subject stops breathing, administer artificial respiration. Get medical advice/attention immediately.
INGESTION: Get medical advice/attention immediately. Do not induce vomiting. Do not administer anything not explicitly authorised by a doctor.

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

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

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

Information not available

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.

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.
When choosing personal protective equipment, ask your chemical substance supplier for advice.
Personal protective equipment must be CE marked, showing that it complies with applicable standards.
Provide an emergency shower with face and eye wash station.
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 II 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.
EYE PROTECTION
Wear airtight protective goggles (see standard EN 166).
In the presence of risks of exposure to splashes or squirts during work, adequate mouth, nose and eye protection should be used to prevent accidental absorption.
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.
Product residues must not be indiscriminately disposed of with waste water or by dumping in waterways.

SECTION 9. Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value	Information
Appearance	solid	
Colour	red	
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	not available	
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.

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:	7,14 mg/kg
ATE (Dermal) of the mixture:	Not classified (no significant component)

CYCLOHEXIMIDE

LD50 (Oral):	2 mg/kg RAT
STA (Oral):	5,001 mg/kg estimate from table 3.1.2 of Annex I of the CLP (figure used for calculation of the acute toxicity estimate of the mixture)

RIFAMPICIN

LD50 (Oral):	1570 mg/kg rat

SKIN CORROSION / IRRITATION

SECTION 11. Toxicological information ... / >>

Causes skin irritation

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

Suspected of causing genetic defects

CARCINOGENICITY

Does not meet the classification criteria for this hazard class

REPRODUCTIVE TOXICITY

May damage fertility or the unborn child

STOT - SINGLE EXPOSURE

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

This product is dangerous for the environment and is toxic for aquatic organisms. In the long term, it have negative effects on acquatic environment.

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 ≥ than 0,1%.

12.6. Endocrine disrupting properties

SECTION 12. Ecological information ... / >>

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. Product residues should be considered special hazardous waste. The hazard level of waste containing this product should be evaluated according to applicable regulations.
Disposal must be performed through an authorised waste management firm, in compliance with national and local regulations.
Waste transportation may be subject to ADR restrictions.
CONTAMINATED PACKAGING
Contaminated packaging must be recovered or disposed of in compliance with national waste management regulations.

SECTION 14. Transport information

14.1. UN number or ID number

ADR / RID, IMDG, IATA: 2811

14.2. UN proper shipping name

ADR / RID: TOXIC SOLID, ORGANIC, N.O.S. (CYCLOHEXIMIDE)
IMDG: TOXIC SOLID, ORGANIC, N.O.S. (CYCLOHEXIMIDE)
IATA: TOXIC SOLID, ORGANIC, N.O.S. (CYCLOHEXIMIDE)

14.3. Transport hazard class(es)

ADR / RID: Class: 6.1 Label: 6.1

IMDG: Class: 6.1 Label: 6.1

IATA: Class: 6.1 Label: 6.1

14.4. Packing group

ADR / RID, IMDG, IATA: I

14.5. Environmental hazards

ADR / RID: Environmentally Hazardous

IMDG: Marine Pollutant

IATA: NO

For Air transport, environmentally hazardous mark is only mandatory for UN 3077 and UN 3082.

SECTION 14. Transport information ... / >>

14.6. Special precautions for user

ADR / RID:	HIN - Kemler: 66 Special provision: -	Limited Quantities: -	Tunnel restriction code: (C/E)
IMDG:	EMS: F-A, S-A	Limited Quantities: -	
IATA:	Cargo: Passengers: Special provision:	Maximum quantity: 50 Kg Maximum quantity: 5 Kg A3, A5	Packaging instructions: 673 Packaging instructions: 666

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: H2-E2

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006
Contained substance
Point 30-75 CYCLOHEXIMIDE

Regulation (EU) 2019/1148 - on the marketing and use of explosives precursors
not applicable

Substances in Candidate List (Art. 59 REACH)
On the basis of available data, the product does not contain any SVHC in percentage ≥ than 0,1%.

Substances subject to authorisation (Annex XIV REACH)
None

Substances subject to exportation reporting pursuant to Regulation (EU) 649/2012:
None

Substances subject to the Rotterdam Convention:
None

Substances subject to the Stockholm Convention:
None

Healthcare controls
Workers exposed to this chemical agent must not undergo health checks, provided that available risk-assessment data prove that the risks related to the workers' health and safety are modest and that the 98/24/EC directive is respected.

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:

Muta. 2	Germ cell mutagenicity, category 2
Repr. 1A	Reproductive toxicity, category 1A
Acute Tox. 2	Acute toxicity, category 2
Acute Tox. 4	Acute toxicity, category 4
Eye Irrit. 2	Eye irritation, category 2
Skin Irrit. 2	Skin irritation, category 2
STOT SE 3	Specific target organ toxicity - single exposure, category 3
Aquatic Chronic 2	Hazardous to the aquatic environment, chronic toxicity, category 2
H341	Suspected of causing genetic defects.
H360	May damage fertility or the unborn child.
H300	Fatal if swallowed.
H302	Harmful if swallowed.
H319	Causes serious eye irritation.
H315	Causes skin irritation.
H335	May cause respiratory irritation.

SECTION 16. Other information ... / >>

H411 Toxic to aquatic life with long lasting effects.

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 as REACH Regulation
- PEC: Predicted environmental Concentration
- PEL: Predicted exposure level
- 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 as for REACH Regulation
- 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)

- 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.