

The product is not classified as dangerous according to Regulation (EC) No 1272/2008 (CLP), is not persistent, bioaccumulative, toxic (PBT) or very persistent and very bioaccumulative (vPvB) as defined in Annex XIII of Regulation (EC) no. 1907/2006 (REACH), is not included in the candidate list of highly disturbing substances (SVHC). Therefore the provision of a Safety Data Sheet is not mandatory (REACH Art. 31). This Information is a voluntary submission of some information that may assist the downstream user in handling the substance.

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

#### 1.1. Product identifier

Trade name:	SYNBALANCE <sup>®</sup> LINE
CAS number:	Not applicable
EC number:	Not applicable
REACH:	Not applicable

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

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

Company:

Roelmi HPC S.r.l. - Via Celeste Milani, 24/26 - 21040 Origgio (VA) - ITALY

Tel: (+39) 02-33510150

Fax (+39) 02-33549210

Competent person responsible for the safety data sheet:

info.msds@roelmihpc.com

#### 1.4. Emergency telephone number

Roelmi HPC Tel: (+39) 02-33510150 (mon-fri 8.30-17.30)

Outside office hours please refer to :

CAV "Osp. Pediatrico Bambino Gesù" Dip. Emergenza e Accettazione DEA	Roma	(+39) 06 68593726
Az. Osp. Univ. Foggia	Foggia	(+39) 800183459
Az. Osp. "A. Cardarelli"	Napoli	(+39) 081-7472870
CAV Policlinico "Umberto I"	Roma	(+39) 06-49978000
CAV Policlinico "A. Gemelli"	Roma	(+39) 06-3054343
Az. Osp. "Careggi" U.O. Tossicologia Medica	Firenze	(+39) 055-7947819
CAV Centro Nazionale di Informazione Tossicologica	Pavia	(+39) 0382-24444
Osp. Niguarda Ca' Granda	Milano	(+39) 02-66101029
Azienda Ospedaliera Papa Giovanni XXII	Bergamo	(+39) 80088330

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### SECTION 2: Hazards identification

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

The product contains non pathogen microorganisms, from the bio safety class I. It is regarded as non-pathogen.

Adverse physicochemical, human health and environmental effects:

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No other hazards

### 2.2. Label elements

Hazard pictograms:

None

Hazard statements:

None

Precautionary statements:

None

Special Provisions:

None

Special provisions according to Annex XVII of REACH and subsequent amendments:

None

### 2.3. Other hazards

vPvB Substances: None - PBT Substances: None

Other Hazards:

No other hazards

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### SECTION 3: Composition/information on ingredients

SynBalance Line contains freeze-dried probiotic powder standardized with food grade excipients, not dangerous following the legislation in force.

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### SECTION 4: First aid measures

#### 4.1. Description of first aid measures

In case of skin contact:

Wash with plenty of water and soap.

In case of eyes contact:

In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.

In case of Ingestion:

Do not under any circumstances induce vomiting. OBTAIN A MEDICAL EXAMINATION IMMEDIATELY.

In case of Inhalation:

Remove casualty to fresh air and keep warm and at rest.

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

None

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

Treatment:

None

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### SECTION 5: Firefighting measures

#### 5.1. Extinguishing media

Suitable extinguishing media:

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Water.

Carbon dioxide (CO<sub>2</sub>).

Extinguishing media which must not be used for safety reasons:

None in particular.

5.2. Special hazards arising from the substance or mixture

Do not inhale explosion and combustion gases.

Burning produces heavy smoke.

5.3. Advice for firefighters

Use suitable breathing apparatus .

Collect contaminated fire extinguishing water separately. This must not be discharged into drains.

Move undamaged containers from immediate hazard area if it can be done safely.

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### SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

Wear personal protection equipment.

Remove persons to safety.

See protective measures under point 7 and 8.

6.2. Environmental precautions

Do not allow to enter into soil/subsoil. Do not allow to enter into surface water or drains.

Retain contaminated washing water and dispose it.

In case of gas escape or of entry into waterways, soil or drains, inform the responsible authorities.

Suitable material for taking up: absorbing material, organic, sand

6.3. Methods and material for containment and cleaning up

Wash with plenty of water.

6.4. Reference to other sections

See also section 8 and 13

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### SECTION 7: Handling and storage

7.1. Precautions for safe handling

Avoid contact with skin and eyes, inhalation of vapours and mists.

Do not eat or drink while working.

See also section 8 for recommended protective equipment.

7.2. Conditions for safe storage, including any incompatibilities

Keep away from food, drink and feed. Store in original sealed containers, between - 18°C and + 4°C, in a dry place, repaired from light or humidity sources

Incompatible materials:

None in particular.

Instructions as regards storage premises:

Adequately ventilated premises.

7.3. Specific end use(s)

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None in particular

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### SECTION 8: Exposure controls/personal protection

8.1. Control parameters

NA

8.2. Exposure controls

Eye protection:

Not needed for normal use. Anyway, operate according good working practices.

Protection for skin:

No special precaution must be adopted for normal use.

Protection for hands:

Not needed for normal use, but the use of sterile gloves is recommended.

Respiratory protection:

Not needed for normal use, but the use of a protective mask is recommended.

Thermal Hazards:

None

Environmental exposure controls:

None

Appropriate engineering controls:

None

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### SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Properties	Value
Appearance and colour:	White cream to beige powder
Odour:	Characteristic
Odour threshold:	N.A.
pH:	N.A.
Melting point / freezing point:	N.A.
Initial boiling point and boiling range:	N.A.
Flash point:	N.A.
Evaporation rate:	N.A.
Solid/gas flammability:	N.A.
Upper/lower flammability or explosive limits:	N.A.
Vapour pressure:	N.A.
Vapour density:	N.A.
Relative density:	N.A.

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Solubility in water:	Slightly soluble
Solubility in oil:	N.A.
Partition coefficient (n-octanol/water):	N.A.
Auto-ignition temperature:	N.A.
Decomposition temperature:	N.A.
Viscosity:	N.A.
Explosive properties:	N.A.
Oxidizing properties:	N.A.

## 9.2. Other information

Properties	Value
Miscibility:	N.A.
Fat Solubility:	N.A.
Conductivity:	N.A.
Substance Groups relevant properties	N.A.

**SECTION 10: Stability and reactivity**

## 10.1. Reactivity

Stable under normal conditions

## 10.2. Chemical stability

Stable under normal conditions

## 10.3. Possibility of hazardous reactions

None.

## 10.4. Conditions to avoid

Stable under normal conditions.

## 10.5. Incompatible materials

None in particular.

## 10.6. Hazardous decomposition products

None.

**SECTION 11: Toxicological information**

## 11.1. Information on toxicological effects

Toxicological information of the substance:

## a) acute toxicity

Not classified

Based on available data, the classification criteria are not met

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- b) skin corrosion/irritation  
Not classified  
Based on available data, the classification criteria are not met
- c) serious eye damage/irritation  
Not classified  
Based on available data, the classification criteria are not met
- d) respiratory or skin sensitisation  
Not classified  
Based on available data, the classification criteria are not met
- e) germ cell mutagenicity  
Not classified  
Based on available data, the classification criteria are not met
- f) carcinogenicity  
Not classified  
Based on available data, the classification criteria are not met
- g) reproductive toxicity  
Not classified  
Based on available data, the classification criteria are not met
- h) STOT-single exposure  
Not classified  
Based on available data, the classification criteria are not met
- i) STOT-repeated exposure  
Not classified  
Based on available data, the classification criteria are not met
- j) aspiration hazard  
Not classified  
Based on available data, the classification criteria are not met

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### SECTION 12: Ecological information

- 12.1. Toxicity  
Adopt good working practices, so that the product is not released into the environment.  
Not classified for environmental hazards  
Based on available data, the classification criteria are not met
- 12.2. Persistence and degradability  
Biodegradable
- 12.3. Bioaccumulative potential  
N.A.
- 12.4. Mobility in soil  
N.A.
- 12.5. Results of PBT and vPvB assessment  
vPvB Substances: None - PBT Substances: None
- 12.6. Other adverse effects  
None

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### SECTION 13: Disposal considerations

#### 13.1. Waste treatment methods

Recover if possible. In so doing, comply with the local and national regulations currently in force.

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### SECTION 14: Transport information

#### 14.1. UN number

#### 14.2. UN proper shipping name

ADR-Shipping Name: NA

IATA-Shipping Name: NA

IMDG-Shipping Name: NA

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

#### 14.4. Packing group

#### 14.5. Environmental hazards

Marine pollutant: No

#### 14.6. Special precautions for user

#### 14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

No

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### SECTION 15: Regulatory information

#### 15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture

Dir. 98/24/EC (Risks related to chemical agents at work)

Dir. 2000/39/EC (Occupational exposure limit values)

Regulation (EC) n. 1907/2006 (REACH)

Regulation (EC) n. 1272/2008 (CLP)

Regulation (EC) n. 790/2009 (ATP 1 CLP) and (EU) n. 758/2013

Regulation (EU) 2015/830

Regulation (EU) n. 286/2011 (ATP 2 CLP)

Regulation (EU) n. 618/2012 (ATP 3 CLP)

Regulation (EU) n. 487/2013 (ATP 4 CLP)

Regulation (EU) n. 944/2013 (ATP 5 CLP)

Regulation (EU) n. 605/2014 (ATP 6 CLP)

Regulation (EU) n. 2015/1221 (ATP 7 CLP)

Restrictions related to the product or the substances contained according to Annex XVII

Regulation (EC) 1907/2006 (REACH) and subsequent modifications:

Restrictions related to the product:

No restriction.

Restrictions related to the substances contained:

No restriction.

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Where applicable, refer to the following regulatory provisions :

Directive 2012/18/EU (Seveso III)  
Regulation (EC) nr 648/2004 (detergents).  
Dir. 2004/42/EC (VOC directive)

Provisions related to directive EU 2012/18 (Seveso III):

N.A.

15.2. Chemical safety assessment

No Chemical Safety Assessment has been carried out for the substance.

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### SECTION 16: Other information

This document was prepared by a competent person who has received appropriate training.

Main bibliographic sources:

ECDIN - Environmental Chemicals Data and Information Network - Joint Research Centre,  
Commission of the European Communities  
SAX's DANGEROUS PROPERTIES OF INDUSTRIAL MATERIALS - Eight Edition - Van  
Nostrand Reinold

The information contained herein is based on our state of knowledge at the above-specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality.

It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.

This MSDS cancels and replaces any preceding release.

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road.
CAS:	Chemical Abstracts Service (division of the American Chemical Society).
CLP:	Classification, Labeling, Packaging.
DNEL:	Derived No Effect Level.
EINECS:	European Inventory of Existing Commercial Chemical Substances.
GefStoffVO:	Ordinance on Hazardous Substances, Germany.
GHS:	Globally Harmonized System of Classification and Labeling of Chemicals.
IATA:	International Air Transport Association.
IATA-DGR:	Dangerous Goods Regulation by the "International Air Transport Association" (IATA).
ICAO:	International Civil Aviation Organization.
ICAO-TI:	Technical Instructions by the "International Civil Aviation Organization" (ICAO).
IMDG:	International Maritime Code for Dangerous Goods.
INCI:	International Nomenclature of Cosmetic Ingredients.
KSt:	Explosion coefficient.



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LC50:	Lethal concentration, for 50 percent of test population.
LD50:	Lethal dose, for 50 percent of test population.
PNEC:	Predicted No Effect Concentration.
RID:	Regulation Concerning the International Transport of Dangerous Goods by Rail.
STEL:	Short Term Exposure limit.
STOT:	Specific Target Organ Toxicity.
TLV:	Threshold Limiting Value.
TWA:	Time-weighted average
WGK:	German Water Hazard Class.