

SAFETY DATA SHEET

According to Regulation 1907/2006/CE

Doc. N° 4240019 rev.1

Date of issue: 13/11/2014

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

Product name : **Gardnerella antimicrobial supplement**
Product Number : 4240019

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

Identified uses : Laboratory chemicals, Selective reagent for microbiology

1.3 Details of the supplier of the safety data sheet

Company : Biolife Italiana S.r.l.
Viale Monza 272, 20128 Milano Italia
Tel : 0039 02 252091
Fax: 0039 02 2576428
E-mail: mktg@biolifeitaliana.it

1.4 Emergency telephone number

Emergency Phone : 0039 02-6610-1029 (Centro Antiveneni Niguarda Ca' Granda- Milano)

2. HAZARDS IDENTIFICATION

2.1 Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008

Respiratory sensitization (Category 1), H334

Skin sensitization (Category 1), H317

For the full text of the H-Statements mentioned in this Section, see Section 16. **Classification according to EU Directives 67/548/EEC or 1999/45/EC**

Xn Harmful R42/43

For the full text of the R-phrases mentioned in this Section, see Section 16.

2.2 Label elements

Labelling according Regulation (EC) No 1272/2008

Pictogram



Signal word Warning

Hazard statement(s)

H317

H334

May cause an allergic skin reaction.

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Precautionary statement(s)

P261

P280

P342 + P311

Avoid breathing dust.

Wear protective gloves.

If experiencing respiratory symptoms: Call a POISON CENTER or doctor/physician.

Supplemental Hazard Statements none

Restricted to professional users.

According to European Directive 67/548/EEC as amended.

Hazard symbol(s) Xn Harmful


 R-phrase(s)
R42/43

May cause sensitisation by inhalation and skin contact.

 S-phrase(s)
S23
S36/37
S45

 Do not breathe vapour.
Wear suitable protective clothing and gloves.
In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible).

2.3 Other hazards – Photosensitizer
3. COMPOSITION/INFORMATION ON INGREDIENTS
3.2 Mixtures
Hazardous ingredients according to Regulation (EC) No 1272/2008

Components	Classification	Concentration
Nalidixic acid sodium salt		
CAS-No 389-08-2 CE-No 206-864-7	Resp. Sens. 1; H334	50 - 100 %
Gentamicin, sulfate (salt)		
CAS-No 1405-41-0 CE-No 215-778-9	Resp. Sens. 1; Skin Sens. 1; H317, H334	10 - 20 %
Amphotericin B		
CAS-No 1397-89-3 CE-No 215-742-2	Skin Irrit. 2; Eye Irrit. 2; STOT SE 3; H315, H319, H335	< 10 %

Hazardous ingredients according to Directive 1999/45/EC

Components	Classification	Concentration
Nalidixic acid sodium salt		
CAS-No 389-08-2 CE-No 206-864-7	Xn, R42/43 50	50 - 100 %
Gentamicin, sulfate (salt)		
CAS-No 1405-41-0 CE-No 215-778-9	Xn, R42/43	10 - 20 %
Amphotericin B		
CAS-No 1397-89-3 CE-No 215-742-2	Xi, R36/37/38	< 10 %

For the full text of the H-Statements and R-Phrases mentioned in this Section, see Section 16

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

If breathed in, move person into fresh air. If not breathing, give artificial respiration. Consult a physician.

In case of skin contact	Wash off with soap and plenty of water. Take victim immediately to hospital. Consult a physician.
In case of eye contact	Flush eyes with water as a precaution.
If swallowed	Never give anything by mouth to an unconscious person. Rinse mouth with water. Consult a physician.

4.2 Most important symptoms and effects, both acute and delayed

The most important known symptoms and effects are described in the labelling (see section 2.2) and/or in section 11.

4.3 Indication of any immediate medical attention and special treatment needed

no data available

5. FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical or carbon dioxide.

5.2 Special hazards arising from the substance or mixture

Carbon oxides, nitrogen oxides (NO_x), Sulphur oxides

5.3 Advice for firefighters

Wear self contained breathing apparatus for fire fighting if necessary.

5.4 Further information

no data available

6. ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

Use personal protective equipment. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust. For personal protection see section 8.

6.2 Environmental precautions

Prevent further leakage or spillage if safe to do so. Do not let product enter drains.

6.3 Methods and materials for containment and cleaning up

Soak up with inert absorbent material and dispose of as hazardous waste. Keep in suitable, closed

containers for disposal.

6.4 Reference to other sections

For disposal see section 13.

7. HANDLING AND STORAGE

7.1 Precautions for safe handling

Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Avoid exposure - obtain special instructions before use.

Provide appropriate exhaust ventilation at places where dust is formed. For precautions see section 2.2.

7.2 Conditions for safe storage, including any incompatibilities

Store in cool place. Keep container tightly closed in a dry and well-ventilated place.

Recommended storage temperature: 2 - 8 °C



7.3 Specific end use(s)

Apart from the uses mentioned in section 1.2 no other specific uses are stipulated

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

Components with workplace control parameters

It doesn't contain substances with occupational exposure limit value.

8.2 Exposure controls

Appropriate engineering controls

Handle in accordance with good industrial hygiene and safety practice. Wash hands before breaks and at the end of workday.

Personal protective equipment

Eye/face protection

Face shield and safety glasses Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU).

Skin protection

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Body Protection

Complete suit protecting against chemicals, The type of protective equipment must be selected according to the concentration and amount of the dangerous substance at the specific workplace.

Respiratory protection

Where risk assessment shows air-purifying respirators are appropriate use a full-face respirator with multi-purpose combination (US) or type ABEK (EN 14387) respirator cartridges as a backup to engineering controls. If the respirator is the sole means of protection, use a full-face supplied air respirator. Use respirators and components tested and approved under appropriate government standards such as NIOSH (US) or GEN (EU).

Control of environmental exposure

Do not let product enter drains.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

a) Appearance	Form: powder Colour: light yellow
b) Odour	no data available
c) Odour Threshold	no data available
d) pH	no data available
e) Melting point/freezing point	no data available
f) Initial boiling point and boiling range	no data available
g) Flash point	no data available
h) Evaporation rate	no data available

i) Flammability (solid, gas)	no data available
j) Upper/lower flammability or explosive limits	no data available
k) Vapour pressure	no data available
l) Vapour density	no data available
m) Relative density	1,000 g/cm ³
n) Water solubility	no data available
o) Partition coefficient: noctanol/water	no data available
p) Auto-ignition temperature	no data available
q) Decomposition temperature	no data available
r) Viscosity	no data available
s) Explosive properties	no data available
t) Oxidizing properties	no data available

9.2 Other safety information no data available

10. STABILITY AND REACTIVITY

10.1 Reactivity	no data available
10.2 Chemical stability	Stable under recommended storage conditions.
10.3 Possibility of hazardous reactions	no data available
10.4 Conditions to avoid	no data available
10.5 Incompatible materials	Oxidizing agents, Strong acids
10.6 Hazardous decomposition products	Other decomposition products - no data available In the event of fire: see section 5

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 sensitisation	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

Aminoglycosides are associated with significant nephrotoxicity and/or ototoxicity., Nausea, Dizziness, To the best of our knowledge, the chemical, physical, and toxicological properties have not been thoroughly investigated.

(Nalidixic acid)

Liver - Irregularities - Based on Human Evidence (Gentamicin, sulfate (salt))

Liver - Irregularities - Based on Human Evidence (Amphotericin B)

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 PBT/vPvB assessment not available as chemical safety assessment not required/not conducted

12.6 Other adverse effects Harmful to aquatic life.

13. DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Product Offer surplus and non-recyclable solutions to a licensed disposal company.

Contaminated packaging Dispose of as unused product.

14. TRANSPORT INFORMATION

14.1 UN number ADR/RID: - IMDG: - IATA: -

14.2 UN proper shipping name ADR/RID: Not dangerous goods
IMDG: Not dangerous goods
IATA: Not dangerous goods

14.3 Transport hazard class(es) ADR/RID: - IMDG: - IATA: -

14.4 Packaging group ADR/RID: - IMDG: - IATA: -

14.5 Environmental hazards ADR/RID: no IMDG Marine Pollutant: no IATA: no

14.6 Special precautions for user no data available

15. REGULATORY INFORMATION

This safety datasheet complies with the requirements of Regulation (EC) No. 1907/2006.

15.1 Safety, health and environmental regulations/legislation specific for the substance or mixture
no data available

15.2 Chemical Safety Assessment

For this product a chemical safety assessment was not carried out

16. OTHER INFORMATION**Full text of H-Statements referred to under sections 2 and 3.**

Eye Irrit.	Eye irritation
H315	Causes skin irritation.
H317	May cause an allergic skin reaction.
H319	Causes serious eye irritation.
H334	May cause allergy or asthma symptoms or breathing difficulties if inhaled.
H335	May cause respiratory irritation.
Resp. Sens.	Respiratory sensitization
Skin Irrit.	Skin irritation
Skin Sens.	Skin sensitization
STOT SE	Specific target organ toxicity - single exposure

Full text of R-phrases referred to under sections 2 and 3

Xi	Irritant
R36/37/38	Irritating to eyes, respiratory system and skin.
R42/43	May cause sensitization by inhalation and skin contact.
Xn	Harmful

Further information

Restrictions for use No data available

Training advice No data available

References No data available

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