

P261

P333+P313

# Biolife Italiana S.r.l.

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4240016 - SKIRROW ANTIMICROBIC SUPPLEMENT

Safety Data Sheet

According to Annex II to REACH - Regulation 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 4240016 Code: Product name SKIRROW ANTIMICROBIC SUPPLEMENT 1.2. Relevant identified uses of the substance or mixture and uses advised against Intended use Supplement for microbiology 1.3. Details of the supplier of the safety data sheet Biolife Italiana S.r.l. Name Full address Viale Monza, 272 District and Country 20128 Milano (Milano) Italia Tel. 0039 02 252091 Fax 0039 02 2576428 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: Skin sensitization, category 1 H317 May cause an allergic skin reaction. 2.2. Label elements Hazard labelling pursuant to EC Regulation 1272/2008 (CLP) and subsequent amendments and supplements. Hazard pictograms: Warning Signal words: Hazard statements: H317 May cause an allergic skin reaction. Precautionary statements: P280 Wear protective gloves.

Avoid breathing dust / fume / gas / mist / vapours / spray.

If skin irritation or rash occurs: Get medical advice / attention.

EN



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ΕN

#### SECTION 2. Hazards identification ... / >>

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Contains: VANCOMYCIN HCL

#### 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 >= 0.1%.

### **SECTION 3. Composition/information on ingredients**

## 3.2. Mixtures

Contains:

Identificationx = Conc. %Classification (EC) 1272/2008 (CLP)VANCOMYCIN HCL<br/>CAS1404-93-9 $8 \le x < 9$ Skin Sens. 1 H317EC

CAS 140 EC INDEX

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. Wash immediately with plenty of water. If irritation persists, get medical advice/attention. Wash contaminated clothing before using it again.

INHALATION: Remove to open air. In the event of breathing difficulties, get medical advice/attention immediately.

INGESTION: Get medical advice/attention. Induce vomiting only if indicated by the doctor. Never give anything by mouth to an unconscious person, unless 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. The product is combustible and, when the powder is released into the air in sufficient concentrations and in the presence of a source of ignition, it can create explosive mixtures with air. Fires may start or get worse by leakage of the solid product from the container, when it reaches high temperatures or through contact with sources of ignition.

#### 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



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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

During the risk assessment process, it is essential to take into consideration the ACGIH occupational exposure levels for inert particulate not otherwise classified (PNOC respirable fraction: 3 mg/m3; PNOC inhalable fraction: 10 mg/m3). For values above these limits, use a P type filter, whose class (1, 2 or 3) must be chosen according to the outcome of risk assessment.

#### 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.



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### SECTION 8. Exposure controls/personal protection ..../>>

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).

RESPIRATORY PROTECTION

Use a type P filtering facemask, whose class (1, 2 or 3) and effective need, must be defined according to the outcome of risk assessment (see standard EN 149).

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 Appearance Colour Odour Melting point / freezing point Initial boiling point Flammability Lower explosive limit Upper explosive limit Flash point Auto-ignition temperature pH Kinematic viscosity Solubility Partition coefficient: n-octanol/water Vapour pressure Density and/or relative density	Value solid powder white Not available Not available
	Not available 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

The powders are potentially explosive when mixed with air.

#### 10.4. Conditions to avoid

Avoid environmental dust build-up.

#### 10.5. Incompatible materials

Information not available

# EN

Information



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SECTION 10. Stability and reactivity ... / >>

#### 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: ATE (Oral) of the mixture: ATE (Dermal) of the mixture: Not classified (no significant component) Not classified (no significant component) Not classified (no significant component)

#### 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

Sensitising for the skin

Respiratory sensitization

Information not available

Skin sensitization

Information not available

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

Adverse effects on sexual function and fertility



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#### SECTION 11. Toxicological information ..../>>

Information not available

Adverse effects on development of the offspring

Information not available

Effects on or via lactation

Information not available

STOT - SINGLE EXPOSURE

Does not meet the classification criteria for this hazard class

Target organ

Information not available

Route of exposure

Information not available

STOT - REPEATED EXPOSURE

Does not meet the classification criteria for this hazard class

Target organ

Information not available

Route of exposure

Information not available

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



#### SECTION 12. Ecological information ... / >>

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. 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. 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.

#### 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: None

Restrictions relating to the product or contained substances pursuant to Annex XVII to EC Regulation 1907/2006



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#### SECTION 15. Regulatory information ... / >>

#### None

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  $\geq$  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:

Skin Sens. 1	Skin sensitization, category 1
H317	May cause an allergic skin reaction.

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



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#### SECTION 16. Other information ... / >>

- 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)

- 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.