

Phoenix Scientific – Amphotericin B 100x- A1001

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

- 1.1 Product identifier:** Amphotericin B 100x -A1001
Other means of identification:
Non-applicable
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**
Relevant uses: Used in biotechnology. For professional users/industrial user only.
Uses advised against: All uses not specified in this section or in section 7.3
- 1.3 Details of the supplier of the safety data sheet:**
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- 1.4 Emergency telephone number:** CIAV (Centro de Informação Antivenenos): +351 800 250 250

SECTION 2: HAZARDS IDENTIFICATION

- 2.1 Classification of the substance or mixture:**
CLP Regulation (EC) No 1272/2008:
The product is not classified as hazardous according to CLP Regulation (EC) No 1272/2008.
- 2.2 Label elements:**
CLP Regulation (EC) No 1272/2008:
None
- 2.3 Other hazards:**
Product fails to meet PBT/vPvB criteria
Endocrine- disrupting properties: the product fails to meet criteria

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

- 3.1 Substance:** Non-applicable
- 3.2 Mixture**
Chemical description: Mixture composed of additives and biocides
Components:
None of the substances contained in the mixture are above the limits specified in Annex II of Regulation (EC) No 1907/2006

SECTION 4: FIRST AID MEASURES

- 4.1 Description of first aid measures:**
Consult a doctor in case of discomfort showing the SDS for the product.
- By inhalation:**
In case of symptoms, move the person affected into fresh air.
- By skin contact:**
In case of contact it is recommended to clean the affected area thoroughly with water and neutral soap. In case of changes to the skin (stinging, redness, rashes, blisters...), seek medical advice with this Safety Data Sheet
- By eye contact:**
Rinse with water until the product has been eliminated. In case of problems, consult a doctor showing the SDS for the product.
- By ingestion/aspiration:**
In case of consumption in large quantities, it is recommended to seek medical assistance.
- 4.2 Most important symptoms and effects, both acute and delayed:**
Acute and delayed effects are indicated in sections 2 and 11.

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SECTION 4: FIRST AID MEASURES

- 4.3 Indication of any immediate medical attention and special treatment needed:**
Non-applicable

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media:

Suitable extinguishing media:

Product is non-flammable, with a low risk of fire due to the flammability characteristics of the product in normal conditions of storage, handling and use. In the case of the existence of sustained combustion as a result of improper handling, storage or use any type of extinguishing agent can be used (ABC Powder, water...)

Unsuitable extinguishing media:

Non-applicable

5.2 Special hazards arising from the substance or mixture:

Due to its non-inflammable nature, the product does not present a fire risk under normal conditions of storage, handling and use.

5.3 Advice for firefighters:

Depending on the magnitude of the fire it may be necessary to use full protective clothing and self-contained breathing apparatus (SCBA). Minimum emergency facilities and equipment should be available (fire blankets, portable first aid kit...) in accordance with Directive 89/654/EC.

Additional provisions:

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Eliminate all sources of ignition. In case of fire, cool the storage containers and tanks for products susceptible to combustion, explosion or BLEVE as a result of high temperatures. Avoid spillage of the products used to extinguish the fire into an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

For non-emergency personnel:

Isolate leaks provided that there is no additional risk for the people performing this task.

For emergency responders:

Wear protective equipment. Keep unprotected persons away. See section 8.

6.2 Environmental precautions:

This product is not classified as hazardous to the environment. Keep product away from drains, surface and ground water.

6.3 Methods and material for containment and cleaning up:

It is recommended:

Absorb the spillage using sand or inert absorbent and move it to a safe place. Do not absorb in sawdust or other combustible absorbents. For any concern related to disposal consult section 13.

6.4 Reference to other sections:

See sections 8 and 13.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling:

A.- General precautions for safe use

Comply with the current legislation concerning the prevention of industrial risks with regards manually handling weights.
Maintain order, cleanliness and dispose of using safe methods (section 6).

B.- Technical recommendations for the prevention of fires and explosions

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SECTION 7: HANDLING AND STORAGE

It is recommended to transfer at a slow speed to avoid the creation of electrostatic charges that could affect flammable products. Consult section 10 for conditions and materials that should be avoided.

C.- Technical recommendations on general occupational hygiene

Do not eat or drink during the process, washing hands afterwards with suitable cleaning products.

D.- Technical recommendations to prevent environmental risks

It is not necessary to take special measures to prevent environmental risks. For more information see subsection 6.2

7.2 Conditions for safe storage, including any incompatibilities:

A.- Technical measures for storage

Store in a cool, dry, well-ventilated location

B.- General conditions for storage

Avoid sources of heat, radiation, static electricity and contact with food. For additional information see subsection 10.5

7.3 Specific end use(s):

Except for the instructions already specified it is not necessary to provide any special recommendation regarding the uses of this product.

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters:

Substances whose occupational exposure limits have to be monitored in the workplace (European OEL, not country-specific legislation):
There is no applicable occupational exposure limits for the substances contained in the product

DNEL (Workers):

Non-applicable

DNEL (General population):

Non-applicable

PNEC:

Non-applicable

8.2 Exposure controls:

A.- Individual protection measures, such as personal protective equipment

As a preventative measure it is recommended to use basic Personal Protective Equipment, with the corresponding <<CE marking>> in accordance with Regulation (EU) 2016/425. For more information on Personal Protective Equipment (storage, use, cleaning, maintenance, class of protection...) consult the information leaflet provided by the manufacturer. For more information see subsection 7.1. All information contained herein is a recommendation which needs some specification from the labor risk prevention services as it is not known whether the company has additional measures at its disposal.

B.- Respiratory protection

The use of protection equipment will be necessary if a mist forms or if the occupational exposure limits are exceeded.

C.- Specific protection for the hands

Non-applicable

D.- Eye and face protection

Non-applicable

E.- Body protection

Non-applicable

F.- Additional emergency measures

It is not necessary to take additional emergency measures.

Environmental exposure controls:

In accordance with the community legislation for the protection of the environment it is recommended to avoid environmental spillage of both the product and its container. For additional information see subsection 7.1.D

Volatile organic compounds:

With regard to Directive 2010/75/EU, this product has the following characteristics:

V.O.C. (Supply): 0 % weight

V.O.C. density at 20 °C: 0 kg/m³ (0 g/L)

Average carbon number: Non-applicable

Average molecular weight: Non-applicable

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties:

For complete information see the product datasheet.

Appearance:

Physical state at 20°C:	Liquid
Appearance:	Not available
Colour:	Yellow
Odour:	Odourless
Odour treshold:	Non-applicable*

Volatility:

Boiling point at atmospheric pressure:	100°C
Vapour pressure at 20°C:	2350 Pa
Vapour pressure at 50°C:	12381,01Pa (12,38 kPa)
Evaporation rate at 20°C:	Non-applicable*

Product description:

Density at 20°C:	1032 kg/m ³
Relative density at 20°C:	1,032
Dynamic viscosity at 20°C:	1,03 cP
Kinematic viscosity at 20°C:	0,99 mm ² /s
Kinematic viscosity at 40°C:	Non-applicable*
Concentration:	Non-applicable*
pH:	10-11,5
Vapour density at 20°C:	Non-applicable*
Partition coefficient n-octanol/water 20°C:	Non-applicable*
Solubility in water at 20°C:	Non-applicable*
Solubility properties:	Insoluble
Decomposition temperature:	Non-applicable*
Melting point/ Freezing point:	Non-applicable*

Flammability:

Flash Point:	Non-Flammable (>60°C)
Flammability (solid, gas):	Non-applicable*
Autoignition temperature:	Non-applicable*
Lower flammability limit:	Non-applicable*
Upper flammability limit:	Non-applicable*

Particle characteristics:

Median equivalent diameter:	Non-applicable*
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9.2 Other information:

Information with regard to physical hazard classes:

Explosive properties:	Non-applicable*
Oxidizing properties:	Non-applicable*
Corrosive to metals:	Non-applicable*
Heat of combustion:	Non-applicable*
Aerosols-total percentage (by mass) of flammable components:	Non-applicable*

Other safety characteristics:

Surface tension at 20°C:	Non-applicable*
Refraction index:	Non-applicable*

*Not relevant due to the nature of the product, not providing information property of its hazards.

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity:

No hazardous reactions are expected because the product is stable under recommended storage conditions. See section 7.

10.2 Chemical stability:

Chemically stable under the indicated conditions of storage, handling and use.

10.3 Possibility of hazardous reactions:

Under the specified conditions, hazardous reactions that lead to excessive temperatures or pressure are not expected.

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SECTION 10: STABILITY AND REACTIVITY

10.4 Conditions to avoid:

Applicable for handling and storage at room temperature:

Shock and friction	Contact with air	Increase in temperature	Sunlight	Humidity
Not applicable	Not applicable	Not applicable	Not applicable	Not applicable

10.5 Incompatible materials:

Acids	Water	Oxidizing Materials	Combustible Materials	Others
Avoid strong acids	Not applicable	Not applicable	Not applicable	Avoid alkalis or strong bases

10.6 Hazardous decomposition products:

See subsection 10.3, 10.4 and 10.5 to find out the specific decomposition products. Depending on the decomposition conditions, complex mixtures of chemical substances can be released: carbon dioxide (CO₂), carbon monoxide and other organic compounds

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on hazard classes as defined in Regulation (EC) No 1272/2008:

LD50 oral > 2000 mg/kg (rat)

Dangerous health implications:

In case of exposure that is repetitive, prolonged or at concentrations higher than the recommended occupational exposure limits, adverse effects on health may result, depending on the means of exposure:

A-Ingestion (acute effect):

- Acute toxicity: Based on available data, the classification criteria are not met
- Corrosivity/Irritability: Based on available data, the classification criteria are not met

B-Inhalation (acute effect):

- Acute toxicity: Based on available data, the classification criteria are not met
- Corrosivity/Irritability: Based on available data, the classification criteria are not met

C-Contact with the skin and the eyes (acute effect):

- Contact with the skin: Based on available data, the classification criteria are not met
- Contact with the eyes: Based on available data, the classification criteria are not met

D-CMR effects (carcinogenicity, mutagenicity and toxicity to reproduction):

- Carcinogenicity: Based on available data, the classification criteria are not met
- IARC: Non-applicable
- Mutagenicity: Based on available data, the classification criteria are not met
- Reproductive toxicity: Based on available data, the classification criteria are not met

E-Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met
- Skin: Based on available data, the classification criteria are not met

F-Specific target organ toxicity (STOT) - single exposure:

Based on available data, the classification criteria are not met

G-Specific target organ toxicity (STOT)-repeated exposure:

- Specific target organ toxicity (STOT)-repeated exposure: Based on available data, the classification criteria are not met
- Skin: Based on available data, the classification criteria are not met

H-Aspiration hazard:

Based on available data, the classification criteria are not met

Other information:

Non-applicable

Specific toxicology information on the substances:

Not available

11.2 Information on other hazards:

Endocrine disrupting properties

Endocrine-disrupting properties: The product fails to meet the criteria.

Other information

Non-applicable

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SECTION 12: ECOLOGICAL INFORMATION

The experimental information related to the eco-toxicological properties of the product itself is not available

- 12.1 Toxicity:**
Not available
- 12.2 Persistence and degradability:**
Not available
- 12.3 Bioaccumulative potential:**
Not available
- 12.4 Mobility in soil:**
Not available
- 12.5 Results of PBT and vPvB assessment:**
Product fails to meet PBT/vPvB criteria
- 12.6 Endocrine disrupting properties:**
Endocrine-disrupting properties: The product fails to meet the criteria.
- 12.7 Other adverse effects:**
Not described

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Code	Description	Waste Class (Regulation (EU) No 1357/2014)
16 05 09	Discarded chemicals other than those mentioned in 16 05 06, 16 05 07 or 16 05 08	Non dangerous

Type of waste (Regulation (EU) No 1357/2014):

Non-applicable

Waste management (disposal and evaluation):

Consult the authorized waste service manager on the assessment and disposal operations in accordance with Annex 1 and Annex 2 (Directive 2008/98/EC). As under 15 01 (2014/955/EC) of the code and in case the container has been in direct contact with the product, it will be processed the same way as the actual product. Otherwise, it will be processed as non-dangerous residue. Waste should not be disposed of to drains. See paragraph 6.2.

Regulations related to waste management:

In accordance with Annex II of Regulation (EC) No 1907/2006 (REACH) the community or state provisions related to waste management are stated

Community legislation: Directive 2008/98/EC, 2014/955/EU, Regulation (EU) No 1357/2014

SECTION 14: TRANSPORT INFORMATION

Transport of Dangerous Goods				
		By Land (ADR 2021 and RID 2021)	By Sea (IMDG 40-20)	By Air (IATA/ICAO 2023)
UN number or ID Number		Non-applicable	Non-applicable	Non-applicable
UN proper shipping name		Non-applicable	Non-applicable	Non-applicable
Transport hazard	Class(es)	Non-applicable	Non-applicable	Non-applicable
	Labels	Non-applicable	Non-applicable	Non-applicable
Packing Group		Non-applicable	Non-applicable	Non-applicable
Environmental hazards		No	No	No
Special precautions for user	Special regulations	Non-applicable	Non-applicable	-
	Tunnel restriction code	Non-applicable	-	-
	Physico-Chemical properties	See section 9	See Section 9	See Section 9
	Limited quantities	Non-applicable	Non-applicable	-
Maritime transport in bulk according to IMO instruments		Non-applicable	Non-applicable	Non-applicable

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SECTION 15: REGULATORY INFORMATION

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

Candidate substances for authorization under the Regulation (EC) No 1907/2006 (REACH): Non-applicable

Substances included in Annex XIV of REACH ("Authorization List") and sunset date: Non-applicable

Regulation (EC) No 1005/2009, about substances that deplete the ozone layer: non-applicable

Article 95, REGULATION (EU) No 528/2012: Non-applicable

REGULATION (EU) No 649/2012, in relation to the import and export of hazardous chemical products: Non-applicable

Seveso III: Non-applicable

Limitations to commercialization and the use of certain dangerous substances and mixtures (Annex XVII REACH, etc):

Non-applicable

Specific provisions in terms of protecting people or the environment:

It is recommended to use the information included in this safety data sheet as a basis for conducting workplace-specific risk assessments in order to establish the necessary risk prevention measures for the handling, use, storage and disposal of this product.

Other legislation:

The product could be affected by sectorial legislation

15.2 Chemical safety assessment:

The supplier has not carried out evaluation of chemical safety.

SECTION 16: OTHER INFORMATION

Legislation related to safety data sheets:

The SDS shall be supplied in an official language of the country where the product is placed on the market. This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) No 1907/2006 (COMMISSION REGULATION (EU) 2020/878).

Texts of the legislative phrases mentioned in section 3:

The phrases indicated do not refer to the product itself; they are present merely for informative purposes and refer to the individual components which appear in section 3

CLP Regulation (EC) No 1272/2008: Non-applicable

Classification procedure: Non-applicable

Advice related to training:

Training is recommended in order to prevent industrial risks for staff using this product and to facilitate their comprehension and interpretation of this safety data sheet, as well as the label on the product.

Principal bibliographical sources:

<http://echa.europa.eu>

<http://eur-lex.europa.eu>

Abbreviations and acronyms:

ADR: European agreement concerning the international carriage of dangerous goods by road

IMDG: International maritime dangerous goods code

IATA: International Air Transport Association

ICAO: International Civil Aviation Organization

COD: Chemical Oxygen Demand

BOD5: 5day biochemical oxygen demand BCF: Bioconcentration factor

LD50: Lethal Dose 50

LC50: Lethal Concentration 50 EC50: Effective concentration 50

LogPOW: Octanolwater partition coefficient

Koc: Partition coefficient of organic carbon

UFI: unique formula identifier

IARC: International Agency for Research on Cancer

The information contained in this safety data sheet is based on sources, technical knowledge and current legislation at European and state level, without being able to guarantee its accuracy. This information cannot be considered a guarantee of the properties of the product; it is simply a description of the security requirements. The occupational methodology and conditions for users of this product are not within our awareness or control, and it is ultimately the responsibility of the user to take the necessary measures to obtain the legal requirements concerning the manipulation, storage, use and disposal of chemical products. The information on this safety data sheet only refers to this product, which should not be used for needs other than those specified.