

Phoenix Scientific – Amphotericin B- 1397-89-3- PA1101



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

1.1

Product identifier: Amphotericin B

CAS: 1397-89-3

Other means of identification:

UFI: WT10-4044-P00H-2M28

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:

Phoenix Scientific, Unipessoal LDA

Rua Afonso de Almeida nº16, V11 8600-674 Lagos, Portugal

Phone: +351308800210

sales@phoenix-scientific.com

www.phoenix-scientific.com

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:

Classification of this product has been carried out in accordance with CLP Regulation (EC) No 1272/2008.

Eye Irrit. 2: Eye irritation, Category 2, H319

Skin Irrit. 2: Skin irritation, Category 2, H315

STOT SE 3: Respiratory tract toxicity, single exposure, Category 3, H335

2.2

Label elements:

CLP Regulation (EC) No 1272/2008:

Warning



Hazard statements:

Eye Irrit. 2: H319 - Causes serious eye irritation.

Skin Irrit. 2: H315 - Causes skin irritation.

STOT SE 3: H335 - May cause respiratory irritation..

Precautionary statements:

P264: Wash thoroughly after handling.

P271: Use only outdoors or in a well-ventilated area.

P280: Wear protective gloves/protective clothing/respiratory protection/eye protection/protective footwear.

P302+P352: IF ON SKIN: Wash with plenty of water.

P304+P340: IF INHALED: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

P403+P233: Store in a well-ventilated place. Keep container tightly closed.

P501: Dispose of contents/container in accordance with regulations on hazardous waste or packaging and packaging waste respectively.

UFI: WT10-4044-P00H-2M28

2.3

Other hazards:

Product fails to meet PBT/vPvB criteria

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

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 **Substance:**

Chemical description: Chemical substance

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SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

Components:

In accordance with Annex II of Regulation (EC) No 1907/2006 (point 3), the product contains:

Identification	Chemical name/ Classification		Concentration
Cas: 1397-89-3	Amphotericin B		100%
EC: 215-742-2	Self-classified		
Index: Non-applicable	Regulation 1272/2008	Eye Irrit.2: H319; Skin Irrit. 2: H315; STOT SE 3: H335- Warning	
REACH: Non-applicable			

To obtain more information on the hazards of the substances consult sections 11,12 and 16.

3.2 Mixture:

Non-applicable

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures:

The symptoms resulting from intoxication can appear after exposure, therefore, in case of doubt, seek medical attention for direct exposure to the chemical product or persistent discomfort, showing the SDS of this product.

By inhalation:

Remove the person affected from the area of exposure, provide with fresh air and keep at rest. In serious cases such as cardiorespiratory failure, artificial resuscitation techniques will be necessary (mouth to mouth resuscitation, cardiac massage, oxygen supply, etc.) requiring immediate medical assistance.

By skin contact: Remove contaminated clothing and footwear, rinse skin or shower the person affected if appropriate with plenty of cold water and neutral soap. In serious cases see a doctor. If the product causes burns or freezing, clothing should not be removed as this could worsen the injury caused if it is stuck to the skin. If blisters form on the skin, these should never be burst as this will increase the risk of infection.

By eye contact: Rinse eyes thoroughly with lukewarm water for at least 15 minutes. Do not allow the person affected to rub or close their eyes. If the injured person uses contact lenses, these should be removed unless they are stuck to the eyes, in which case this could cause further damage. In all cases, after cleaning, a doctor should be consulted as quickly as possible with the SDS of the product.

By ingestion/aspiration: Do not induce vomiting, but if it does happen keep the head down to avoid aspiration. Keep the person affected at rest. Rinse out the mouth and throat, as they may have been affected during ingestion.

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

Acute and delayed effects are indicated in sections 2 and 11.

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:

As a result of combustion or thermal decomposition reactive sub-products are created that can become highly toxic and, consequently, can present a serious health risk.

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SECTION 5: FIREFIGHTING MEASURES

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 in to an aqueous medium.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures:

For non-emergency personnel:

Sweep up and shovel product or collect by other means and place in container for reuse (preferred) or disposal

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: Sweep up and shovel product or collect by other means and place in container for reuse (preferred) or disposal

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. Keep containers hermetically sealed. Control spills and residues, destroying them with safe methods (section 6). Avoid leakages from the container. Maintain order and cleanliness where dangerous products are used.

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

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

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 recommended to have absorbent material available at close proximity to the product (See subsection 6.3)

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.

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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):

Nuisance dust: Inhalable dust 10 mg/m³ // Respirable dust 4 mg/m³

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

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory respiratory tract protection	Filter mask for gases, vapours and particles		EN 149:2001+A1:2009 EN 405:2002+A1:2010 EN ISO 136:1998	Replace when an increase in resistance to breathing is observed and/or a smell or taste of the contaminant is detected.



C.- Specific protection for the hands

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory hand protection	Protective gloves against minor risks			Replace gloves in case of any sign of damage. For prolonged periods of exposure to the product for professional users/industrials, we recommend using CE III gloves in line with standards EN ISO 21420:2020 and EN ISO 374-1:2016 + A1:2018

D.- Eye and face protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory face protection	Panoramic glasses against splash/projections		EN 166:2002 EN ISO 4007:2018	Clean daily and disinfect periodically according to the manufacture's instructions. Use if there is a risk of splashing



E.- Body protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
	Work clothing			Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 6529:2013, EN ISO 6530:2005, EN ISO 13688:2013, EN 464:1994.
Pictogram	PPE	Labelling	CEN Standard	Remarks
	Anti-slip work shoes		EN ISO 20347:2012	Replace before any evidence of deterioration. For periods of prolonged exposure to the product for professional/industrial users CE III is recommended, in accordance with the regulations in EN ISO 20345:2012 and EN ISO 13832-1:2007



SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

F.- Additional emergency measures

Emergency Measure	Standards	Emergency Measure	Standard
 Emergency shower	ANSI Z358-1 ISO 3864-1:2011, ISO 3864-4:2011	 Eyewash stations	DIN 12 899 ISO 3864-1:2011, ISO 3864-4:2011

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

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: Solid
- Appearance: Powdery
- Colour: Orange
- Odour: Not available
- Odour treshold: Non-applicable*

Volatility:

- Boiling point at atmospheric pressure: Non-applicable*
- Vapour pressure at 20°C: Non-applicable*
- Vapour pressure at 50°C: Non-applicable*
- Evaporation rate at 20°C: Non-applicable*

Product description:

- Density at 20°C: Non-applicable*
- Relative density at 20°C: Non-applicable*
- Dynamic viscosity at 20°C: Non-applicable*
- Kinematic viscosity at 20°C: Non-applicable*
- Kinematic viscosity at 40°C: Non-applicable*
- Concentration: Non-applicable*
- pH: 4,8-5,6
- 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: Non-applicable*
- Decomposition temperature: Non-applicable*
- Melting point/ Freezing point: Non-applicable*

Flammability:

- Flammability (solid, gas): Non-applicable*
- Autoignition temperature: Non-applicable*
- Upper flammability limit: Non-applicable*

Explosive (solid):

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

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SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

Lower explosive limit:	Non-applicable*
Upper explosive limit:	Non-applicable*
Particle characteristics:	
Median equivalent diameter:	Non-applicable*

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.

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:

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

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, as it does not contain substances classified as hazardous for consumption. For more information see section 3
- Corrosivity/Irritability: The consumption of a considerable dose can cause irritation in the throat, abdominal pain, nausea and vomiting.

B-Inhalation (acute effect):

- Acute toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for inhalation. For more information see section 3.
- Corrosivity/Irritability: Causes irritation in respiratory passages, which is normally reversible and limited to the upper respiratory passages.

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

- Contact with the skin: Produces skin inflammation.
- Contact with the eyes: Produces eye damage after contact.



SECTION 11: TOXICOLOGICAL INFORMATION

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

- Carcinogenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for the effects mentioned. For more information see section 3.

IARC: Non-applicable

- Mutagenicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

- Reproductive toxicity: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

E-Sensitizing effects:

- Respiratory: Based on available data, the classification criteria are not met. However, it contains substances classified as dangerous with sensitizing effects. For more information see section 3.

- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

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

Causes irritation in respiratory passages, which is normally reversible and limited to the upper respiratory passages.

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, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

- Skin: Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

H-Aspiration hazard:

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

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

SECTION 12: ECOLOGICAL INFORMATION

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

Based on available data, the classification criteria are not met, as it does not contain substances classified as hazardous for this effect. For more information see section 3.

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

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SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods:

Code	Description	Waste Class (Regulation (EU) No 1357/2014)
	It is not possible to assign a specific code, as it depends on the intended use by the user	Hazardous

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

HP5 Specific Target Organ Toxicity (STOT)/Aspiration Toxicity, HP4 Irritant — skin irritation and eye damage

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 2023 and RID 2023)	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	
	Labels	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	-	
	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	

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

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SECTION 15: REGULATORY INFORMATION

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 2:

H315: Causes skin irritation.

H335: May cause respiratory irritation.

H319: Causes serious eye irritation.

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:

Eye Irrit. 2: H319 - Causes serious eye irritation.

Skin Irrit. 2: H315 - Causes skin irritation.

STOT SE 3: H335 - May cause respiratory irritation.

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

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.