




**Amphotericin B - 1397-89-3**  
**PM-A4121**

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

- 1.1 Product identifier:** Amphotericin B  
CAS: 1397-89-3  
EC: 215-742-2  
Index: Non-applicable  
REACH: Non-applicable
- 1.2 Relevant identified uses of the substance or mixture and uses advised against:**  
Relevant uses:  
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:**  
BIOSERA FRANCE SAS  
Rue de la Caille  
49340 Nuaille - France  
Phone : 00 33 5 61 97 69 69  
Email : info@biosera.com  
www.biosera.com
- 1.4 Emergency telephone number:** ORFILA: 01 45 42 59 59

**SECTION 2: HAZARDS IDENTIFICATION**

- 2.1 Classification of the substance or mixture:**  
**CLP Regulation (EC) n° 1272/2008:**  
Classification of this product has been carried out in accordance with CLP Regulation (EC) n° 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) n° 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 use  
P271: Use only outdoors or in a well-ventilated area  
P280: Wear protective gloves/protective clothing/eye protection/face protection  
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 and / or containers in accordance with regulations on hazardous waste or packaging and packaging waste respectively
- 2.3 Other hazards:**  
Non-applicable

**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS**

- 3.1 Substance:**

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**SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS (continued)**

**Chemical description:**

**Components:**

In accordance with Annex II of Regulation (EC) n°1907/2006 (point 3), the product contains:

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

To obtain more information on the risk of the substances consult sections 8, 11, 12, 15 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, as 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:**

Product is non-flammable under normal conditions of storage, manipulation and use. In the case of inflammation as a result of improper manipulation, storage or use preferably use polyvalent powder extinguishers (ABC powder), in accordance with the Regulation on fire protection systems. IT IS NOT RECOMMENDED to use tap water as an extinguishing agent.

**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.

**5.3 Advice for firefighters:**

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

**Additional provisions:**

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**SECTION 5: FIREFIGHTING MEASURES (continued)**

Act in accordance with the Internal Emergency Plan and the Information Sheets on actions to take after an accident or other emergencies. Destroy any source of ignition. In case of fire, refrigerate the storage containers and tanks for products susceptible to inflammation, 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:**

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

**6.2 Environmental precautions:**

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

**6.3 Methods and material for containment and cleaning up:**

It is recommended:

Sweep up and shovel product or 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.- Precautions for safe manipulation

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, manipulation and use.

C.- Technical recommendations to prevent ergonomic and toxicological risks

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.

**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION**

**8.1 Control parameters:**

Substances whose occupational exposure limits have to be monitored in the work environment

Nuisance dust: Inhalable dust 10 mg/m<sup>3</sup> // Respirable dust 4 mg/m<sup>3</sup>

**DNEL (Workers):**

Non-applicable

**DNEL (General population):**

Non-applicable

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**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)**

**PNEC:**

Non-applicable



**8.2 Exposure controls:**

A.- General security and hygiene measures in the work place



As a preventative measure it is recommended to use basic Personal Protection Equipment, with the corresponding <<CE marking>> in accordance with Directive 89/686/EC. For more information on Personal Protection 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 labour 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 405:2001+A1:2009	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 420 and EN 374.

D.- Ocular and facial protection



Pictogram	PPE	Labelling	CEN Standard	Remarks
 Mandatory face protection	Panoramic glasses against liquid splash		EN 166:2001 EN ISO 4007:2012	Clean daily and disinfect periodically according to the manufacturer's instructions. Use if there is a risk of splashing.

E.- Bodily protection

Pictogram	PPE	Labelling	CEN Standard	Remarks
	Work clothing			
	Anti-slip work shoes		EN ISO 20347:2012	

F.- Additional emergency measures

It is not necessary to take additional emergency measures.

Emergency measure	Standards	Emergency measure	Standards
 Emergency shower	ANSI Z358-1 ISO 3864-1:2002	 Eyewash stations	DIN 12 899 ISO 3864-1:2002

**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:

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**SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION (continued)**

V.O.C. (Supply):	0 % weight
V.O.C. density at 20 °C:	0 kg/m <sup>3</sup> (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
Color:	 Orange
Odor:	Not available

**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:	Non-applicable *
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 *
Explosive properties:	Non-applicable *
Oxidising properties:	Non-applicable *

**Flammability:**

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

**9.2 Other information:**

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.

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**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 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	Combustive 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 (CO<sub>2</sub>), carbon monoxide and other organic compounds.

**SECTION 11: TOXICOLOGICAL INFORMATION**

**11.1 Information on toxicological effects:**

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 recommended by the occupational exposure limits, it may result in adverse effects on health 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 dangerous 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 dangerous 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.

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

E- Sensitizing effects:

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

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**SECTION 11: TOXICOLOGICAL INFORMATION (continued)**

- 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 dangerous 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 dangerous 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 dangerous for this effect. For more information see section 3.

**Other information:**

Non-applicable

**Specific toxicology information on the substances:**

Not available

**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:**

Non-applicable

**12.6 Other adverse effects:**

Not described

**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	Dangerous

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

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

**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. We do not recommend disposal down the drain. See paragraph 6.2.

**Regulations related to waste management:**

In accordance with Annex II of Regulation (EC) n°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:**

With regard to ADR 2015 and RID 2015:

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**SECTION 14: TRANSPORT INFORMATION (continued)**

- 14.1 UN number:** Non-applicable
- 14.2 UN proper shipping name:** Non-applicable
- 14.3 Transport hazard class(es):** Non-applicable
- Labels: Non-applicable
- 14.4 Packing group:** Non-applicable
- 14.5 Dangerous for the environment:** No
- 14.6 Special precautions for user**
- Special regulations: Non-applicable
- Tunnel restriction code: Non-applicable
- Physico-Chemical properties: see section 9
- Limited quantities: Non-applicable
- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:** Non-applicable

**Transport of dangerous goods by sea:**

With regard to IMDG 37-14:

- 14.1 UN number:** Non-applicable
- 14.2 UN proper shipping name:** Non-applicable
- 14.3 Transport hazard class(es):** Non-applicable
- Labels: Non-applicable
- 14.4 Packing group:** Non-applicable
- 14.5 Dangerous for the environment:** No
- 14.6 Special precautions for user**
- Special regulations: Non-applicable
- EmS Codes:
- Physico-Chemical properties: see section 9
- Limited quantities: Non-applicable
- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:** Non-applicable

**Transport of dangerous goods by air:**

With regard to IATA/ICAO 2015:

- 14.1 UN number:** Non-applicable
- 14.2 UN proper shipping name:** Non-applicable
- 14.3 Transport hazard class(es):** Non-applicable
- Labels: Non-applicable
- 14.4 Packing group:** Non-applicable
- 14.5 Dangerous for the environment:** No
- 14.6 Special precautions for user**
- Physico-Chemical properties: see section 9
- 14.7 Transport in bulk according to Annex II of Marpol and the IBC Code:** Non-applicable

**SECTION 15: REGULATORY INFORMATION**

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

Candidate substances for authorisation under the Regulation (EC) 1907/2006 (REACH): Non-applicable  
Substances included in Annex XIV of REACH ("Authorisation List") and sunset date: Non-applicable  
Regulation (EC) 1005/2009, about substances that deplete the ozone layer: Non-applicable  
Article 95, REGULATION (EU) No 528/2012: Non-applicable

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**SECTION 15: REGULATORY INFORMATION (continued)**

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

**Limitations to commercialisation 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 data used in a risk evaluation of the local circumstances in order to establish the necessary risk prevention measures for the manipulation, 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:**

This safety data sheet has been designed in accordance with ANNEX II-Guide to the compilation of safety data sheets of Regulation (EC) N° 1907/2006 (Regulation (EU) N° 453/2010, Regulation (EC) N° 2015/830)

**Modifications related to the previous security card which concerns the ways of managing risks. :**

Non-applicable

**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) n° 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:**

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

**Principal bibliographical sources:**

<http://esis.jrc.ec.europa.eu>

<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 Organisation

COD: Chemical Oxygen Demand

BOD5: 5-day biochemical oxygen demand

BCF: Bioconcentration factor

LD50: Lethal Dose 50

CL50: Lethal Concentration 50

EC50: Effective concentration 50

Log-POW: Octanol-water partition coefficient

Koc: Partition coefficient of organic carbon

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.

- END OF SAFETY DATA SHEET -