

SAFETY DATA SHEET

Date of Original Issue: 09DEC2005

Revision Number: 8

Revision Date: 06SEP2022

SECTION 1: Identification Of The Substance/Mixture And Of The Company/Undertaking

1.1 Product identifier

Product name: Amphotericin B API

CAS #: 1397-89-3

EC/List #: 215-742-2

INDEX #: Not listed

REACH reg. #: Not listed

1.2 Relevant identified uses of the substance or mixture

Product Name: Amphotericin B

Product Use: Anti-infective

Synonyms: Amphotericin

1.3 Details of the responsible party of the safety data sheet

Manufacturer

Xellia Pharmaceuticals ApS

Dalslandsgade 11

2300 Copenhagen S

Denmark

+45 3264 5500

Responsible person for the safety data sheet (e-mail): sales@xellia.com

1.4 Emergency telephone number

Poison Control Center (USA): +1 877 800 5553

CHEMTREC (USA Transportation): +1 800 424 9300

CANUTREC (Canadian Transportation): +1 613 996 6666

UN #: No applicable information found

COMMENTS: To the best of our knowledge, this MSDS conforms to the requirements of USA OSHA 29 CFR 1910.1200, 1907/2006/EC, 453/2010/EC and Canadian Hazardous Products Act. You are urged to consider laws and regulations applicable to your state and country.

SECTION 2: Hazards Identification

2.1 Classification of the substance or mixture

Eye Irritation – Category 1B; Specific Target Organ Toxicity (Repeated Exposure) – Category 2

2.2 Label elements

Content: Amphotericin B



DANGER

H318: Causes serious eye damage
 H373: Causes damage to organs through prolonged or repeated exposure
 P260: Do not breathe dust/fume/gas/mist/vapors/spray.
 P264+P265: Wash hands thoroughly after handling. Do not touch eyes.

P280: Wear protective gloves/protective clothing/eye protection/face protection.
 P305+P354+P338: IF IN EYES: Immediately rinse with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
 P317: Get emergency medical help.
 P319: Get medical help if you feel unwell.
 P501: Dispose of contents/container appropriately.

2.3 Other Hazards:

None known.

PBT/vPvB: The substance is not considered PBT/vPvB according to criteria in Annex XIII.

SECTION 3: Composition/Information On Ingredients

3.1 Substances:

Active component	Hazards Classification	CAS#	EU/List #
Amphotericin B	Eye Irritation – Category 1B; Specific Target Organ Toxicity (Repeated Exposure) – Category 2	1397-89-3	215-742-2

Comments: Product composition ranges shown are typical values for health, safety and environmental use and are not intended as specifications.

SECTION 4: First Aid Measures

4.1 Description of first aid measures

Eye contact: Flush eyes for 15 minutes with plenty of water. Get medical attention immediately.

Skin contact: Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation or rash develops.

Ingestion: Do not induce vomiting. Call a physician or poison control center. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

Inhalation: Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

4.2 Most important symptoms and effects, both acute and delayed

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: Allergy to amphotericin B.

4.3 Indication of any immediate medical attention and special treatment needed

In case of discomfort or unconsciousness: Show this safety data sheet to a physician or emergency center, treat symptomatically.

SECTION 5: Firefighting Measures

5.1 Extinguishing media

Water, carbon dioxide, dry chemical, foam, or other alternatives.

5.2 Special hazards arising from the substance or mixture

General hazards:	May be combustible at high temperature. Fine particles (such as dust and mists) may fuel fires/explosions.
Hazardous combustion products:	Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides.
Unsuitable extinguishing media:	None
Specific methods:	Not available

5.3 Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: Accidental Release Measures

6.1 Personal precautions, protective equipment, and emergency response

Wear personal protective equipment to avoid exposure – see section 8. Avoid generation of dust.

6.2 Environmental precautions

Water spill:	Do not empty into drains.
Land spill:	Vacuum material with appropriate dust collection in place. Be aware of potential for dust explosion when using electrical equipment. If a vacuum is not available, lightly mist material and remove by sweeping or wet wiping. Wear appropriate equipment including eye protection, to avoid exposure.
Release notes:	If the spill could potentially enter any waterway, including intermittent dry creeks, contact the local authorities. In the USA, contact the USA Coast Guard National Response Center toll free +1 800 424 8802.

6.3 Methods and materials for containment and cleaning up

Contain dry material by lightly misting with water, followed by sweeping carefully so as not to generate dust, or vacuuming. Ensure the vacuum is fitted with an appropriate dust filter so dust is not re-introduced into the air. Be aware of the potential for dust explosion when using electrical equipment.

6.4 References to other sections

See section 1 for emergency contact information, section 8 for personal protective equipment details, and section 13 for disposal information.

SECTION 7: Handling And Storage

7.1 Precautions for safe handling

- For large quantities:** Engineering controls are recommended to ensure adequate ventilation such that exposures do not exceed exposure limits. With adequate ventilation respiratory protection may not be needed. In the absence of adequate ventilation, suitable respiratory protection is required. The need for additional personal protective equipment including respirators, eye and skin protection should be based on a job-specific risk assessment. Additional personal protective equipment may include chemical-resistant gloves and body covering, goggles, and face shield. Adequate eye protection is always required.
- For small quantities:** Keep dry and away from sources of ignition. Keep the bottle tightly closed when not in use.
- Work hygienic practices:** Facilities storing or using this material should be equipped with an emergency eyewash and safety shower. Good personal hygiene practices should always be followed.

7.2 Conditions for safe storage, including any incompatibilities

Store securely, inaccessible for unauthorized persons. Keep dry and away from sources of ignition.

7.3 Specific end uses

See section 1.

SECTION 8: Exposure Controls/Personal Protection

8.1 Control parameters

OSHA'S hazardous components (29 CFR 1910.1020) EXPOSURE LIMITS AND GUIDELINES

	<u>OSHA PEL</u>		<u>ACGIH TLV</u>		<u>OTHER OEL (TWA)</u>	
	<u>ppm</u>	<u>mg/m³</u>	<u>ppm</u>	<u>mg/m³</u>	<u>ppm</u>	<u>mg/m³</u>
Amphotericin B (CAS #: 1397-89-3)	NL	NL	NL	NL	NL	0.07

Other country exposure limits: Not listed.

This product does not contain any hazardous materials with occupational exposure established by the region-specific regulatory bodies

8.2 Exposure controls

Appropriate engineering controls: If dust is generated, provide local exhaust ventilation to control airborne levels below the OEL listed above.

PERSONAL PROTECTIVE EQUIPMENT:

- Eyes and face:** Wear safety glasses with side shields or goggles as appropriate when handling this material.
- Skin:** Chemical resistant gloves (nitrile or latex) and body covering.
- Respiratory:** Use an approved respirator suitable to provide level of protection required.
- Comments:** This product is not specifically listed by OSHA as hazardous. Under conditions of overexposure, this product may be hazardous.

SECTION 9: Physical And Chemical Properties

9.1 Information on basic physical and chemical properties

- Physical state:** Solid
- Appearance:** Yellow powder

Color:	Yellow
Odor:	Odorless
Odor threshold:	Not relevant
pH:	No applicable information found
Vapor pressure:	No applicable information found
Vapor density:	No applicable information found
Evaporation rate:	No applicable information found
Freezing point:	No applicable information found
Melting point:	No applicable information found
Boiling point:	No applicable information found
Flash point:	No applicable information found
Decomposition temperature:	No applicable information found
Flammability:	No applicable information found
Upper/lower flammability or explosive limits (vol-%):	No applicable information found
Auto-ignition temperature:	No applicable information found
Soluble in water:	Insoluble
Density:	No applicable information found
Specific gravity:	No applicable information found
Viscosity:	No applicable information found
Explosive properties:	No applicable information found
Oxidizing properties:	No applicable information found
Molecular formula:	C ₄₇ H ₇₃ N O ₁₇
Molecular weight:	924.1
Coefficient of oil and water:	-2.8 (estimated)

9.2 OTHER INFORMATION:

Not available.

SECTION 10: Stability And Reactivity

10.1 Reactivity

No data available.

10.2 Chemical stability

Stable under recommended storage conditions.

10.3 Possibility of hazardous reactions

Hazardous polymerization has not been reported.

10.4 Conditions to avoid

Incompatible materials, dust generation, excess heat, alkaline materials, strong oxidants, exposure to moist air or water.

10.5 Incompatible materials

Strong oxidants, moisture.

10.6 Hazardous decomposition products

Nitrogen oxides, carbon monoxide, oxides of sulfur, irritating and toxic fumes and gases, carbon dioxide.

SECTION 11: Toxicological Information

11.1 Information on toxicological effects

Acute oral LD50: >5000 mg/ kg (rat)

Acute inhalation LC50: >0.968 mg/ l (rat)

Eye effects: Irritant

Skin effects: Irritant

Sensitization: Allergic rashes and anaphylaxis including swelling of the hands, feet, and lips, a choking sensation, shortness of breath and decreased blood pressure have been reported from repeated exposure.

Target organ: Cardiovascular system (arrhythmias, hypertension, damage to heart muscle); eyes (loss of vision); blood (anemia); skin (rash); muscle (pain); neurologic (headache); kidney (impaired function); and gastrointestinal (bleeding).

Carcinogenicity: Not determined

Listed by IARC: No **Listed by NTP:** No **Listed by OSHA:** No

Mutagenicity: Not determined

Reproductive effects: Not determined

Teratogenic effects: Not determined

SECTION 12: Ecological Information

12.1 Toxicity

No applicable information found. Releases to the environment should be avoided.

12.2 Persistence and degradability

No applicable information found.

12.3 Bio-accumulative potential

Log K_{ow} = -2.8 (estimated). No significant potential for bioaccumulation.

12.4 Mobility in soil

No applicable information found.

12.5 Results of PBT and vPvB assessment

The substance is not considered PBT/vPvB according to criteria in Annex XIII.

12.6 Other adverse effects

The substance is possibly harmful for the aquatic environment, due to its antibiotic properties.

SECTION 13: Disposal Considerations

13.1 Waste treatment methods: Do not empty into drain. Dispose of any cleanup materials and waste residue according to applicable laws and regulations.

SECTION 14: Transport Information

14.1 UN Number

Not Regulated.

14.2 UN proper shipping name

Not Regulated.

14.3 Transport hazard class(es)

Not Regulated.

14.4 Packing group

Not Regulated.

14.5 Environmental hazards

Not Regulated.

14.6 Special precautions for user

Not Regulated.

14.7 Transport in bulk according to Annex II Marpol 73/78 and the IBC code

Not relevant.

USA DOT (DEPARTMENT OF TRANSPORTATION)

Proper Shipping Name: Not regulated

CANADA TRANSPORT OF DANGEROUS GOODS

Proper Shipping Name: Not regulated.

AIR (ICAO/IATA)

Proper Shipping Name: Not regulated.

VESSEL (IMO/IMDG)

Proper Shipping Name: Not regulated.

EUROPEAN TRANSPORTATION:

ADR/RID HAZARD CLASSIFICATION: Not Regulated.

U.S. CUSTOMS HARMONIZATION NUMBER: Not Available.

SECTION 15: Regulatory Information

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

EUROPEAN COMMUNITY

Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (CLP Regulation)

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH),

Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work:

Must not be used by persons under 18 years of age.

Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding:

The employer shall assess the working conditions and, if there is any risk to the safety or health and any effects on the pregnancy or breastfeeding of workers, take the necessary measures to adjust the working conditions.

Implementation of directive 2001/82/EC of the European Parliament and of the council of 6 November 2001 in the Community code relating to veterinary medical products:

Denmark: The Danish Medicines Agency (Lægemiddelstyrelsen) must be notified that this substance is produced, imported, exported, stored, sold, delivered, packed, possessed or in other ways handled in Denmark (Bekendtgørelse nr. 1226 af 7 December 2005 om omgang med visse stoffer og produkter hvis indhold kan anvendes som lægemidler til dyr.).

For other countries: Please contact national authorities regarding notification of the substance.

UNITED STATES FEDERAL REGULATIONS

Superfund Amendments and Reauthorization Act (SARA) Title III 311/312 hazard categories:

Fire: No **Pressure generating:** No **Reactivity:** No **Acute:** No **Chronic:** No

313 Reportable Ingredients:

Title III notes:

Comprehensive Response, Compensation, and Liability Act (CERCLA)

CERCLA RQ: Not listed

Toxic Substances Control Act (TSCA)

TSCA Regulatory: Not listed

National Response Center: US Coast Guard National Center Response Telephone
+1 800 424 8802.

UNITED STATES STATE REGULATIONS

California Proposition 65: This product does not contain chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

CANADA

Workplace Hazardous Material Information System (WHMIS) hazard symbol and classification

WHMIS Controlled: Not regulated.

Canadian Environmental Protection Act: Not listed

15.2 Chemical safety assessment

No CSR.

SECTION 16: Other information

Reason for issue: New Document

Contact Information: See Section 1.

Revision summary: Eighth issue.

Disclaimer: Information given herein is offered in good faith as accurate, but without guarantee. Conditions of use and suitability of the product for uses are beyond our control; all risks of use of the product are therefore assumed by the user. Nothing is intended as a recommendation for uses that infringe valid patents or as extending license under valid patents. Appropriate warnings and safe handling procedures should be provided to handlers and users.

Glossary:

ACGIH – American Conference of Governmental Hygienists

AIHA – American Industrial Hygiene Association

BEI – Biological Exposure Index

CAS – Chemical Abstract Service Registry Number

CSR – Chemical Safety Report
CERCLA – Comprehensive Environmental Response Compensation and Liability Act of 1989
CHEMTREC – Chemical Transportation Emergency Center
DOT – Department of Transportation (USA)
EC – European Community
EINECS – European Inventory of Existing Chemical Substances
ELINCS - European List of New Chemical Substances
EPA – Environmental Protection Agency
FDA – United States Food and Drug Administration
HEPA- High Efficiency Particulate Air (Filter)
HMIS – Hazardous Material Information System
IARC- International Agency on Research for Cancer Page 7 of 7
ICAO/IATA – International Civil Aviation Organization/International Air Transport Association
IMO – International Maritime Organization
LEL – Lower Explosive Limit
MSDS – Material Safety Data Sheet
MSHA – Mine Safety and Health Administration
NA – Not Applicable
NADA – New Animal Drug Application
NAIF – No Applicable Information Found
NCI – National Cancer Institute
ND – Not Determined
NFPA – National Fire Protection Association
NIOSH – National Institute for Occupational Health and Safety
NL – Not Listed
NOS – Not Otherwise Specified
NTP – National Toxicology Program
OEL – Occupational Exposure Limit
OSHA – Occupational Safety and Health Administration
PEL – Permissible Exposure Limit (USA)
RCRA – Resource Conservation and Recovery Act
RQ – Reportable Quantity
RTECS – Registry of Toxic Effects of Chemical Substances
SARA – Superfund Amendments and Reauthorization Act
STEL – Short Term Exposure Limit
TLV – Threshold Limit Value
TPQ – Threshold Planning Quantity
TSCA – Toxic Substances Control Act
TWA – Time Weighted Average
UEL – Upper Explosive Limit
UN – United Nations
WEEL – Workplace Environmental Exposure Level (USA - AIHA)
