

SAFETY DATA SHEET

Date of Original Issue: 09DEC2005

Revision Number: 11

Revision: 21MAR2024

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1. Product identifier

Product name: Amphotericin B

Identification number: 1032007

CAS #: 1397-89-3

EC/List #: 215-742-2

INDEX #: Not listed

REACH reg. #: Not registered, exempted

1.2. Relevant identified uses of the substance or mixture and uses advised against

Product Use: Pharmaceutical product used as anti-infective agent

1.3. Details of the supplier of the safety data sheet

Manufacturer & Distributor

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

<http://apps.who.int/poisoncentres/>

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Classification according to Regulation (EC) No 1272/2008:

Skin Irrit. 2, Eye Irrit. 2, STOT SE 3 (irrit.), STOT RE 2 (kidney)

2.2. Label elements



WARNING

H315: Causes skin irritation.

H319: Causes serious eye irritation.

H335: May cause respiratory irritation.
 H 373: May cause damage to kidney through prolonged or repeated exposure.
 P 260: Do not breathe dust/fume/gas/mist/vapors/spray.
 P 264: Wash hands thoroughly after handling.
 P 261: Avoid breathing dust/fume/gas/mist/vapors/spray.
 P 270: Do not eat, drink, or smoke when using this product.

P 314: Get Medical advice/attention if you feel unwell.
 P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses if present and easy to do - continue rinsing.
 P 303. +P.361 +P.353: IF ON SKIN (or hair): Remove/Take off immediately all contaminated clothing. Rinse skin with water [or shower].

2.3. Other hazards

PBT/vPvB: The substance is not considered PBT/vPvB according to criteria in Annex XIII neither has properties of endocrine disruption.

SECTION 3: Composition/information on ingredients

3.1. Substances

Active component	CAS #	EC/List #
Amphotericin B	1397-89-3	215-742-2

SECTION 4: First aid measures

4.1. Description of first aid measures

General information: Remove the injured person from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health practitioner or other licensed health care provider familiar with chemical exposure in the workplace.

Eye contact: Flush eyes for 15 minutes with plenty of water. Remove contact lenses, if any, and this is easy to do. Continue rinsing. Consult a specialist if irritation develops and persists.

Skin contact: Remove and clean contaminated clothing and footwear before reuse. Wash the affected area of skin with soapy water. In case of development and persistence of skin irritation, swelling or redness, consult a doctor. In case of eczema or other skin diseases, consult a doctor.

Ingestion: After ingestion of large amounts, a poison center or doctor. Do not induce vomiting. Wash your mouth. Do not give anything orally to an unconscious person. Consult a doctor if symptoms occur. When vomiting, keep your head low so that stomach contents do not get into the lungs.

Inhalation: The person concerned should be taken out to fresh air and placed in a resting position such that he or she can breathe easily. If the injured person is unconscious and not breathing: Ensure that there are no obstructions in the airways and have artificial respiration performed by appropriately trained persons. If necessary, apply external heart massage and consult a doctor

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

Symptoms and Effects of Exposure: Pharmacologically active substance. Occupational exposure may cause physiological effects. Renal impairment.

Medical Conditions Aggravated by Exposure: None

4.3. Indication of any immediate medical attention and special treatment needed.

General support measures, symptomatic treatment Activated charcoal should be administered as an aqueous suspension within one hour of ingestion, unless contraindicated. Monitor the patient for possible ototoxicity, nephrotoxicity, hematopoietic or heart disease. Peritoneal dialysis can be effective in cleaning serum. Hemoperfusion, hemofiltration and hemodiafiltration can remove the substance from the blood if high porosity hemofilters are used.

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: Explosion hazard: Avoid dust formation; fine dust scattered in the air in sufficient concentration and in the presence of an ignition source constitutes a potential dust explosion hazard.

Unsuitable extinguishing media: None

Specific methods: Not available

5.3. Advice for firefighters

Wear appropriate protective equipment. Use water spray to cool unopened containers. As with any fire, evacuate personnel to a safe area.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment, and emergency procedures

Keep away unnecessary staff. Wear appropriate protective equipment. Avoid inhaling dust from spills. Do not touch damaged containers or spills unless you wear appropriate protective clothing. Ensure adequate ventilation. Dust deposits should not accumulate on surfaces, as they can form explosive mixtures if released into the atmosphere in appropriate concentrations. For personal protection, see Section 8 of the Safety Data Sheet.

6.2. Environmental precautions

Water spill: In case of intrusion into inland waters or sewers, notify the competent authorities. Do not allow to enter sewer/surface water/groundwater.

6.3. Methods and materials for containment and cleaning up.

Avoid dust build-up during cleaning. Spilled material must be swept or vacuumed and collected in a suitable container for disposal. To remove residual dirt, thoroughly clean the surface. For waste disposal, see section 13 of the safety data sheet.

6.4. Reference 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: As a rule, avoid contact with and inhalation of dust, mist and/or vapors associated with the substance. After use, clean equipment and work surfaces with an appropriate detergent or solvent. After removing gloves, wash hands thoroughly and wash exposed skin. Significant deposits of substances should be avoided, especially on horizontal surfaces, which can be released into the air, form flammable dust clouds, and contribute to secondary explosions. Flammable dust clouds can form when operations produce fine matter (dust). Choose and use closed systems and personal protective equipment based on a risk assessment based on exposure and hazard of the substance.

7.2. Conditions for safe storage, including any incompatibilities.

Store securely, inaccessible for unauthorized persons. Keep dry and away from sources of ignition. Store at 2°C - 8°C (36°F - 46°F) in original, unopened package or container.

7.3. Specific end use(s)

See section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

OEL for the substance: 0.03 mg/m³.

8.2. Exposure controls

Appropriate engineering controls: For laboratory operations, use a local exhaust ventilation or ventilated chamber for high-energy operations such as shredding. Choose and use enclosed equipment and personal protective equipment based on the risk assessment. During transportation, cover all containers for storing solutions and suspensions.

Personal protective equipment:

Eyes protection: If contact is likely, safety glasses with lateral protection must be used.

Hand protection: Wear chemically resistant gloves (tested according to EN 374) while completing training specific to the specific activity. The gloves should be regularly inspected and replaced for wear, tearing or contamination.

Skin: Laboratory clothes.

Respiratory protection: As a rule, a respirator is not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters to clean spills. Respiratory protection adapted to the task and the level of existing technical controls.

Comments: This product may cause kidney and nervous system damage from overexposure to amphotericin B, based on clinical use as described in the Physicians Desk Reference. Under conditions of overexposure, this product may be hazardous.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

a)	Physical state	solid powder
b)	Color	yellow orange
c)	Odor	odorless

d)	Melting point/freezing point	>170°C
e)	Boiling point or starting boiling point and boiling point range	No measured data available
f)	Flammability	Can be burned but not classified
g)	Upper/lower flammability or explosive limits	Not applicable for solids
h)	Flash point	Not applicable for solids
i)	Auto-ignition temperature	No measured data available
j)	Decomposition temperature	287°C
k)	pH	No measured data available
l)	Kinematic viscosity	Not applicable for solids
m)	Solubility	750mg/L at 28°C in water. It dissolves in dimethylformamide or dimethylsulfoxide
n)	Partition coefficient: N-octanol/water (log value)	0.8
o)	Vapour pressure	<0.0000001 kPa 25 °C - on
p)	Density and/or relative density	No measured data available
q)	Relative vapour density	Not applicable for solids
r)	Particle characteristics	No measured data available

9.2. Other information

Dust explosion properties

Kst: 218/bar.m/s

Minimum ignition energy (MIE) dust cloud 58 – 62 mJ

SECTION 10: Stability and reactivity

10.1. Reactivity

The product is stable and does not respond under normal conditions of use, storage, and transportation.

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

Under normal conditions, they are not known.

10.4. Conditions to avoid.

Contact with incompatible materials.

10.5. Incompatible materials

Oxidants.

10.6. Hazardous decomposition products

Irritant and/or toxic fumes and gases. In case of fire, it emits toxic fumes: NO_x SO_x.

SECTION 11: Toxicological information

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

a) Acute toxicity

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

Acute oral LD12: 280mg/kg (Mouse)

b) **Intravenous injection:** may cause renal impairment, cardiac toxicity based on information from therapeutic use.

c) **Skin corrosion/skin irritation:** There are no satisfactory test results. Classified for irritation.

d) **Severe eye damage/irritation:** There are no satisfactory test results. Classified for irritation.

e) **Respiratory or skin sensitization:** There are no satisfactory test results.

f) **Germ cell mutagenicity:** There are no satisfactory test results.

Carcinogenicity: There are no satisfactory test results.

Reproductive toxicity: Amphotericin B is recommended as the preferred treatment of cryptococcus infection during pregnancy.

Single post-exposure specific target organ toxicity (STOT): STOT SE 3, classified for irritation.

Specific target organ toxicity (STOT) after repeated exposure: With repeated or prolonged exposure, it can damage kidneys.

Aspiration hazard: Based on its chemical structure, the product is not classified.

11.2. Information on other hazards

No further relevant information available.

SECTION 12: Ecological information

12.1. Toxicity

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

12.2. Persistence and degradability

No applicable information found.

12.3. Bioaccumulative potential

No applicable information found.

12.4. Mobility in soil

No applicable information found.

12.5. Results of PBT and vPvB assessment

No such evaluation of the product has been carried out.

12.6. Endocrine disrupting properties

No such properties are known to the substance.

12.7. Other adverse effects

No applicable information found.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Waste treatment methods Dispose of in accordance with all applicable regulations.

SECTION 14: Transport information

14.1. UN Number or ID 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. Maritime transport in bulk according to IMO instruments

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 UNION

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: Not Listed

Title III notes:

Comprehensive Response, Compensation, and Liability Act (CERCLA)

CERCLA RQ: Not listed.

Toxic Substances Control Act (TSCA)

TSCA Regulatory: Exempt

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 is compiled because the substance is exempted.

SECTION 16: Other information

Reason for issue: Update to include 2020/878 EU Commission regulation. Updated some physical parameters.

Disclaimer: Information given herein is offered in good faith as accurate, but without guarantee. Nothing is intended as a recommendation for uses that infringe valid patents or as extending license under valid patents.
