

SAFETY DATA SHEETS

According to the UN GHS revision 8

Version: 1.0

Creation Date: July 15, 2024

Revision Date: July 15, 2024

1. Identification

1.1 GHS Product identifier

Product name Amphotericin B

1.2 Other means of identification

Product number A10079

Other names

1.3 Recommended use of the chemical and restrictions on use

Identified uses Industrial and scientific research uses.

Uses advised against no data available

1.4 Supplier's details

Company Tianjin Psaitong Biomedical Technology Co., Ltd

Beijing Psaitong Biotechnology Co., Ltd

Address Building 145, Yougu New Science Park, Qingguang Town, Beichen District, Tianjin City

Tel/Fax +86-10-60605840

1.5 Emergency phone number

Emergency phone number +86-10-60605840

Service hours Monday to Friday, 9am-5pm (Standard time zone: UTC/GMT +8 hours).

2. Hazard identification

2.1 Classification of the substance or mixture

Skin irritation, Category 2

Eye irritation, Category 2

Specific target organ toxicity – single exposure, Category 3

2.2 GHS label elements, including precautionary statements

Pictogram(s)



Signal word Warning

Hazard statement(s) H315 Causes skin irritation

H319 Causes serious eye irritation

H335 May cause respiratory irritation

Precautionary statement(s)

Prevention

P264 Wash ... thoroughly after handling.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

Response	<p>P261 Avoid breathing dust/fume/gas/mist/vapours/spray.</p> <p>P271 Use only outdoors or in a well-ventilated area.</p> <p>P302+P352 IF ON SKIN: Wash with plenty of water/...</p> <p>P321 Specific treatment (see ... on this label).</p> <p>P332+P313 If skin irritation occurs: Get medical advice/attention.</p> <p>P362+P364 Take off contaminated clothing and wash it before reuse.</p> <p>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> <p>P337+P313 If eye irritation persists: Get medical advice/attention.</p> <p>P304+P340 IF INHALED: Remove person to fresh air and keep comfortable for breathing.</p> <p>P312 Call a POISON CENTER/doctor/...if you feel unwell.</p>
Storage	<p>P403+P233 Store in a well-ventilated place. Keep container tightly closed.</p> <p>P405 Store locked up.</p>
Disposal	<p>P501 Dispose of contents/container to an appropriate treatment and disposal facility in accordance with applicable laws and regulations, and product characteristics at time of disposal.</p>

2.3 Other hazards which do not result in classification

no data available

3. Composition/information on ingredients

3.1 Substances

Chemical name	Common names and synonyms	CAS number	EC number	Concentration
Amphotericin B	Amphotericin B	1397-89-3	215-742-2	100%

4. First-aid measures

4.1 Description of necessary first-aid measures

General advice

Medical attention is required. Consult a doctor. Show this safety data sheet (SDS) to the doctor in attendance.

If inhaled

Move the victim into fresh air. If breathing is difficult, give oxygen. If not breathing, give artificial respiration and consult a doctor immediately. Do not use mouth to mouth resuscitation if the victim ingested or inhaled the chemical.

Following skin contact

Take off contaminated clothing immediately. Wash off with soap and plenty of water. Consult a doctor.

Following eye contact

Rinse with pure water for at least 15 minutes. Consult a doctor.

Following ingestion

Rinse mouth with water. Do not induce vomiting. Never give anything by mouth to an unconscious person. Call a doctor or Poison Control Center immediately.

4.2 Most important symptoms/effects, acute and delayed

SYMPTOMS: Symptoms of exposure to this compound (through ingestion) may include fever; anorexia; flushing; generalized pain; convulsions; chills; phlebitis; headache; anemia; anaphylaxis; thrombocytopenia; vomiting; mild renal tubular acidosis; decreased renal function; hypokalemia; hypomagnesemia; nerve palsies, including foot drop; weight loss; malaise; dyspepsia; diarrhea; azotemia; hyposthenuria; nephrocalcinosis; and less frequently, anuria; oliguria; arrhythmias; ventricular fibrillation; cardiac arrest; hypertension; hypotension; coagulation effects; leukopenia; agranulocytosis; eosinophilia; melena or hemorrhagic gastroenteritis; rash; hearing loss; tinnitus; transient vertigo; and blurred vision. ACUTE/CHRONIC HAZARDS: When heated to decomposition this compound emits toxic fumes of NO_x. (NTP, 1992)

4.3 Indication of immediate medical attention and special treatment needed, if necessary

In the event of overdosage with any amphotericin B formulation, therapy with the drug should be discontinued and the patient's

clinical status (eg, cardiorespiratory, renal, and liver function, hematologic status, serum electrolytes) monitored. Supportive therapy should be administered as required. ... The patient's condition should be stabilized, including correction of electrolyte abnormalities, prior to reinstating amphotericin B therapy.

5. Fire-fighting measures

5.1 Extinguishing media

Suitable extinguishing media

Fires involving this material can be controlled with a dry chemical, carbon dioxide or Halon extinguisher. (NTP, 1992)

5.2 Specific hazards arising from the chemical

Flash point data for this chemical are not available. It is probably combustible. (NTP, 1992)

5.3 Special protective actions for fire-fighters

Wear self-contained breathing apparatus for firefighting if necessary.

6. Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

Avoid dust formation. Avoid breathing mist, gas or vapours. Avoid contacting with skin and eye. Use personal protective equipment. Wear chemical impermeable gloves. Ensure adequate ventilation. Remove all sources of ignition. Evacuate personnel to safe areas. Keep people away from and upwind of spill/leak.

6.2 Environmental precautions

Prevent further spillage or leakage if it is safe to do so. Do not let the chemical enter drains. Discharge into the environment must be avoided.

6.3 Methods and materials for containment and cleaning up

Collect and arrange disposal. Keep the chemical in suitable and closed containers for disposal. Remove all sources of ignition. Use spark-proof tools and explosion-proof equipment. Adhered or collected material should be promptly disposed of, in accordance with appropriate laws and regulations.

7. Handling and storage

7.1 Precautions for safe handling

Handling in a well ventilated place. Wear suitable protective clothing. Avoid contact with skin and eyes. Avoid formation of dust and aerosols. Use non-sparking tools. Prevent fire caused by electrostatic discharge steam.

7.2 Conditions for safe storage, including any incompatibilities

Conventional amphotericin B powder for injection should be stored at 2-8 deg C. Reconstituted colloidal dispersions of conventional amphotericin B should be protected from light and are stable for 24 hours at room temperature or 1 week when refrigerated at 2-8 deg C. Although the manufacturers state that reconstituted dispersions or IV infusions of amphotericin B should be protected from light during administration, potency is unaffected if the infusion is exposed to light for less than 8-24 hours.

8. Exposure controls/personal protection

8.1 Control parameters

Occupational Exposure limit values

no data available

8.2 Appropriate engineering controls

Ensure adequate ventilation. Handle in accordance with good industrial hygiene and safety practice. Set up emergency exits and the risk-elimination area.

8.3 Individual protection measures, such as personal protective equipment (PPE)

Eye/face protection

Wear tightly fitting safety goggles with side-shields conforming to EN 166(EU) or NIOSH (US).

Skin protection

Wear fire/flammable resistant and impervious clothing. Handle with gloves. Gloves must be inspected prior to use. Wash and dry hands. The selected protective gloves have to satisfy the specifications of EU Directive 89/686/EEC and the standard EN 374 derived from it.

Respiratory protection

If the exposure limits are exceeded, irritation or other symptoms are experienced, use a full-face respirator.

Thermal hazards

no data available

9. Physical and chemical properties

Physical state	PHYSICAL DESCRIPTION: Bright yellow powder. (NTP, 1992)
Colour	Deep yellow prisms or needles from n,n-dimethylformamide
Odour	ODORLESS OR PRACTICALLY SO
Melting point/ freezing point	>170°C
Boiling point or initial boiling point and boiling range	1140.4°C at 760 mmHg
Flammability	no data available
Lower and upper explosion limit / flammability limit	no data available
Flash point	643.5°C
Auto-ignition temperature	no data available
Decomposition temperature	no data available
pH	no data available
Kinematic viscosity	no data available
Solubility	less than 1 mg/mL at 70° F (NTP, 1992)
Partition coefficient n-octanol/water	no data available
Vapour pressure	0mmHg at 25°C
Density and/or relative density	1.34
Relative vapour density	no data available
Particle characteristics	no data available

10. Stability and reactivity

10.1 Reactivity

This chemical is sensitive to prolonged exposure to light and air. Insoluble in water.

10.2 Chemical stability

Solids and solutions appear stable for long periods between pH 4 and 10 when stored at moderate temperature out of light and air.

10.3 Possibility of hazardous reactions

Aqueous solutions may be more stable over prolonged periods of exposure to air and light if kept between pH 4 and 10. This compound yields a volatile base in concentrated sodium hydroxide and can bleach KMnO₄ or Br₂CCl₄. (NTP, 1992)

10.4 Conditions to avoid

no data available

10.5 Incompatible materials

no data available

10.6 Hazardous decomposition products

When heated to decomposition it emits toxic fumes of /nitrogen oxides/.

11. Toxicological information

Acute toxicity

- Oral: no data available
- Inhalation: no data available
- Dermal: no data available

Skin corrosion/irritation

no data available

Serious eye damage/irritation

no data available

Respiratory or skin sensitization

no data available

Germ cell mutagenicity

no data available

Carcinogenicity

no data available

Reproductive toxicity

no data available

STOT-single exposure

no data available

STOT-repeated exposure

no data available

Aspiration hazard

no data available

12. Ecological information

12.1 Toxicity

- Toxicity to fish: no data available
- Toxicity to daphnia and other aquatic invertebrates: no data available
- Toxicity to algae: no data available
- Toxicity to microorganisms: no data available

12.2 Persistence and degradability

no data available

12.3 Bioaccumulative potential

no data available

12.4 Mobility in soil

no data available

12.5 Other adverse effects

no data available

13. Disposal considerations

13.1 Disposal methods

Product

The material can be disposed of by removal to a licensed chemical destruction plant or by controlled incineration with flue gas scrubbing. Do not contaminate water, foodstuffs, feed or seed by storage or disposal. Do not discharge to sewer systems.

Contaminated packaging

Containers can be triply rinsed (or equivalent) and offered for recycling or reconditioning. Alternatively, the packaging can be punctured to make it unusable for other purposes and then be disposed of in a sanitary landfill. Controlled incineration with flue gas scrubbing is possible for combustible packaging materials.

14. Transport information

14.1 UN Number

ADR/RID: Not dangerous goods. (For reference only, please check.)

IMDG: Not dangerous goods. (For reference only, please check.)

IATA: Not dangerous goods. (For reference only, please check.)

14.2 UN Proper Shipping Name

ADR/RID: Not dangerous goods. (For reference only, please check.)

IMDG: Not dangerous goods. (For reference only, please check.)

IATA: Not dangerous goods. (For reference only, please check.)

14.3 Transport hazard class(es)

ADR/RID: Not dangerous goods. (For reference only, please check.)

IMDG: Not dangerous goods. (For reference only, please check.)

IATA: Not dangerous goods. (For reference only, please check.)

14.4 Packing group, if applicable

ADR/RID: Not dangerous goods. (For reference only, please check.)

IMDG: Not dangerous goods. (For reference only, please check.)

IATA: Not dangerous goods. (For reference only, please check.)

14.5 Environmental hazards

ADR/RID: No

IMDG: No

IATA: No

14.6 Special precautions for user

no data available

14.7 Transport in bulk according to Annex II of MARPOL 73/78 and the IBC Code

no data available

15. Regulatory information

15.1 Safety, health and environmental regulations specific for the product in question

Chemical name	Common names and synonyms	CAS number	EC number
Amphotericin B	Amphotericin B	1397-89-3	215-742-2
European Inventory of Existing Commercial Chemical Substances (EINECS)			Listed.
EC Inventory			Listed.
United States Toxic Substances Control Act (TSCA) Inventory			Not Listed.
China Catalog of Hazardous chemicals 2015			Not Listed.
New Zealand Inventory of Chemicals (NZIoC)			Listed.
Philippines Inventory of Chemicals and Chemical Substances (PICCS)			Listed.
Vietnam National Chemical Inventory			Not Listed.
Chinese Chemical Inventory of Existing Chemical Substances (China IECSC)			Listed.
Korea Existing Chemicals List (KECL)			Not Listed.

16. Other information

Information on revision

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Abbreviations and acronyms

- CAS: Chemical Abstracts Service
- ADR: European Agreement concerning the International Carriage of Dangerous Goods by Road
- RID: Regulation concerning the International Carriage of Dangerous Goods by Rail
- IMDG: International Maritime Dangerous Goods
- IATA: International Air Transportation Association
- TWA: Time Weighted Average
- STEL: Short term exposure limit
- LC50: Lethal Concentration 50%
- LD50: Lethal Dose 50%
- EC50: Effective Concentration 50%

References

- IPCS - The International Chemical Safety Cards (ICSC), website: <http://www.ilo.org/dyn/icsc/showcard.home>
- HSDB - Hazardous Substances Data Bank, website: <https://toxnet.nlm.nih.gov/newtoxnet/hsdb.htm>
- IARC - International Agency for Research on Cancer, website: <http://www.iarc.fr/>
- eChemPortal - The Global Portal to Information on Chemical Substances by OECD, website: http://www.echemportal.org/echemportal/index?pageID=0&request_locale=en
- CAMEO Chemicals, website: <http://cameochemicals.noaa.gov/search/simple>
- ChemIDplus, website: <http://chem.sis.nlm.nih.gov/chemidplus/chemidlite.jsp>
- ERG - Emergency Response Guidebook by U.S. Department of Transportation, website: <http://www.phmsa.dot.gov/hazmat/library/erg>
- Germany GESTIS-database on hazard substance, website: <http://www.dguv.de/ifa/gestis/gestis-stoffdatenbank/index-2.jsp>
- ECHA - European Chemicals Agency, website: <https://echa.europa.eu/>

Disclaimer: The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. We as supplier shall not be held liable for any damage resulting from handling or from contact with the above product.