



SAFETY DATA SHEET

Conforms to Regulation (EC) No. 1907/2006 (REACH), Annex II, as amended by Commission Regulation (EU) 2015/830 - Europe

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

1.1 Product identifier

Product name	Amphotericin B (Fungizone) Solution 250 ug/ mL
Catalogue Number	SV30078
Product description	Not available.
Product type	Liquid.
Other means of identification	Not available.

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

F For Further Manufacturing or Research Use. Not for Diagnostic or Therapeutic Use.

1.3 Details of the supplier of the safety data sheet

Supplier

Cytiva Austria
Krempstr. 5
4061 Pasching
AUSTRIA
Phone: +43 7229 64865

HyClone Laboratories
925 West 1800 South
Logan, Utah 84321
Phone: (435) 792-8000

Cytiva Singapore
1 Maritime Square #13-01
Harbourfront Centre
Singapore 099253

Hours of operation

Mo. - Fr.
08.30 - 17.00

Person who prepared the SDS: sds_author@cytiva.com

Europe

Cytiva Austria
Krempstr. 5
4061 Pasching
AUSTRIA
Phone: +43 7229 64865

1.4 Emergency telephone number

Call INFOTRAC 24 Hour number:
001-352-323-3500 (Call Collect).

National advisory body/Poison Centre

Europe <http://www.eapcct.org> -> Go to: Links

SECTION 2: Hazards identification

2.1 Classification of the substance or mixture

Product definition Mixture

Classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Not classified.

The product is not classified as hazardous according to Regulation (EC) 1272/2008 as amended.

Ingredients of unknown toxicity Not applicable.

Ingredients of unknown ecotoxicity Not applicable.

See Section 16 for the full text of the H statements declared above.

See Section 11 for more detailed information on health effects and symptoms.

2.2 Label elements

Hazard pictograms

Signal word No signal word.

Hazard statements No known significant effects or critical hazards.

Precautionary statements

General Not applicable.

Prevention Not applicable.

Response Not applicable.

Storage Not applicable.

Disposal Not applicable.

Hazardous ingredients

Supplemental label elements Not applicable.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles Not applicable.

Special packaging requirements

Containers to be fitted with child-resistant fastenings Not applicable.

Tactile warning of danger Not applicable.

2.3 Other hazards

Product meets the criteria for PBT or vPvB according to Regulation (EC) No. 1907/2006, Annex XIII

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

Other hazards which do not result in classification None known.

SECTION 3: Composition/information on ingredients

3.2 Mixtures Mixture

There are no ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as hazardous to health or the environment, are PBTs or vPvBs or have been assigned a workplace exposure limit and hence require reporting in this section.

Type

- [1] Substance classified with a physical, health or environmental hazard
 [2] Substance with a workplace exposure limit
 [3] Substance meets the criteria for PBT according to Regulation (EC) No. 1907/2006, Annex XIII
 [4] Substance meets the criteria for vPvB according to Regulation (EC) No. 1907/2006, Annex XIII
 [5] Substance of equivalent concern
 [6] Additional disclosure due to company policy

SECTION 4: First aid measures

4.1 Description of first aid measures

Eye contact	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Get medical attention if irritation occurs.
Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. Get medical attention if symptoms occur.
Skin contact	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur.
Ingestion	Wash out mouth with water. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Do not induce vomiting unless directed to do so by medical personnel. Get medical attention if symptoms occur.
Protection of first-aiders	No action shall be taken involving any personal risk or without suitable training.

4.2 Most important symptoms and effects, both acute and delayed

Over-exposure signs/symptoms

Eye contact	No specific data.
Inhalation	No specific data.
Skin contact	No specific data.
Ingestion	No specific data.

4.3 Indication of any immediate medical attention and special treatment needed

Notes to physician	Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled.
Specific treatments	No specific treatment.

See toxicological information (Section 11)

SECTION 5: Firefighting measures

5.1 Extinguishing media

Suitable extinguishing media Use an extinguishing agent suitable for the surrounding fire.

Unsuitable extinguishing media None known.

5.2 Special hazards arising from the substance or mixture

Hazards from the substance or mixture In a fire or if heated, a pressure increase will occur and the container may burst.

Hazardous combustion products No specific data.

5.3 Advice for firefighters

Special precautions for fire-fighters Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training.

Special protective equipment for fire-fighters Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode. Clothing for fire-fighters (including helmets, protective boots and gloves) conforming to European standard EN 469 will provide a basic level of protection for chemical incidents.

SECTION 6: Accidental release measures

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Put on appropriate personal protective equipment.

For emergency responders If specialised clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel".

6.2 Environmental precautions

Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air).

6.3 Methods and material for containment and cleaning up

Small spill Stop leak if without risk. Move containers from spill area. Dilute with water and mop up if water-soluble. Alternatively, or if water-insoluble, absorb with an inert dry material and place in an appropriate waste disposal container. Dispose of via a licensed waste disposal contractor.

Large spill Stop leak if without risk. Move containers from spill area. Prevent entry into sewers, water courses, basements or confined areas. Wash spillages into an effluent treatment plant or proceed as follows. Contain and collect spillage with non-combustible, absorbent material e.g. sand, earth, vermiculite or diatomaceous earth and place in container for disposal according to local regulations. Dispose of via a licensed waste disposal contractor.

6.4 Reference to other sections

See Section 1 for emergency contact information.
See Section 8 for information on appropriate personal protective equipment.
See Section 13 for additional waste treatment information.

SECTION 7: Handling and storage

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

7.1 Precautions for safe handling

Protective measures Put on appropriate personal protective equipment (see Section 8).

Advice on general occupational hygiene Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures.

7.2 Conditions for safe storage, including any incompatibilities

Store in accordance with local regulations. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabelled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

7.3 Specific end use(s)

Recommendations Not available.

Industrial sector specific solutions Not available.

SECTION 8: Exposure controls/personal protection

The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

8.1 Control parameters

Occupational exposure limits

No exposure limit value known.

Recommended monitoring procedures

If this product contains ingredients with exposure limits, personal, workplace atmosphere or biological monitoring may be required to determine the effectiveness of the ventilation or other control measures and/or the necessity to use respiratory protective equipment. Reference should be made to monitoring standards, such as the following: European Standard EN 689 (Workplace atmospheres - Guidance for the assessment of exposure by inhalation to chemical agents for comparison with limit values and measurement strategy) European Standard EN 14042 (Workplace atmospheres - Guide for the application and use of procedures for the assessment of exposure to chemical and biological agents) European Standard EN 482 (Workplace atmospheres - General requirements for the performance of procedures for the measurement of chemical agents) Reference to national guidance documents for methods for the determination of hazardous substances will also be required.

DNELs/DMELs

No DELs available.

PNECs

No PECs available.

8.2 Exposure controls

Appropriate engineering controls Good general ventilation should be sufficient to control worker exposure to airborne contaminants.

Individual protection measures

Hygiene measures	Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.
Eye/face protection	Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields.
Skin protection	
Hand protection	Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary.
Body protection	Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Other skin protection	Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.
Respiratory protection	Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.
Environmental exposure controls	Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

SECTION 9: Physical and chemical properties

The conditions of measurement of all properties are at standard temperature and pressure unless otherwise indicated.

9.1 Information on basic physical and chemical properties**Appearance**

Physical state	Liquid.
Colour	Clear Yellowish
Odour	Not available.
Odour threshold	Not available.
pH	Not available.
Melting point/freezing point	Not available.
Initial boiling point and boiling range	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or explosive limits	Not available.
Flash point	Not available.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Solubility(ies)	Not available.
Solubility in water	Not available.
Partition coefficient: n-octanol/water	Not applicable.
Vapour pressure	Not available.

Ingredient name	Vapour Pressure at 20 °C			Vapour pressure at 50 °C		
	mm Hg	kPa	Method	mm Hg	kPa	Method
Water	23.8	3.2				

Evaporation rate	Not available.
Relative density	Not available.
Vapour density	Not available.
Explosive properties	Not available.
Oxidising properties	Not available.

Particle characteristics

Median particle size	Not applicable.
-----------------------------	-----------------

9.2 Other information

Burning time	Not applicable.
Burning rate	Not applicable.
Solubility in water	Not available.

SECTION 10: Stability and reactivity

10.1 Reactivity	No specific test data related to reactivity available for this product or its ingredients.
10.2 Chemical stability	The product is stable.
10.3 Possibility of hazardous reactions	Under normal conditions of storage and use, hazardous reactions will not occur.
10.4 Conditions to avoid	No specific data.
10.5 Incompatible materials	No specific data.
10.6 Hazardous decomposition products	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

SECTION 11: Toxicological information**11.1 Information on toxicological effects****Acute toxicity**

Conclusion/Summary	Not available.
---------------------------	----------------

Acute toxicity estimates

N/A

Irritation/Corrosion

Conclusion/Summary	Not available.
---------------------------	----------------

Sensitiser

Conclusion/Summary	Not available.
---------------------------	----------------

Mutagenicity

Conclusion/Summary	Not available.
---------------------------	----------------

Carcinogenicity

Conclusion/Summary	Not available.
---------------------------	----------------

Reproductive toxicity

Conclusion/Summary	Not available.
---------------------------	----------------

Teratogenicity

Conclusion/Summary	Not available.
---------------------------	----------------

Specific target organ toxicity (single exposure)

Not available.

Specific target organ toxicity (repeated exposure)

Not available.

Aspiration hazard

Not available.

Information on likely routes of exposure	Routes of entry anticipated: Oral, Dermal, Inhalation.
---	--

Potential acute health effects

Inhalation	No known significant effects or critical hazards.
Ingestion	No known significant effects or critical hazards.
Skin contact	No known significant effects or critical hazards.
Eye contact	No known significant effects or critical hazards.

Symptoms related to the physical, chemical and toxicological characteristics

Inhalation	No specific data.
Ingestion	No specific data.
Skin contact	No specific data.
Eye contact	No specific data.

Delayed and immediate effects as well as chronic effects from short and long-term exposure**Short term exposure**

Potential immediate effects Not available.

Potential delayed effects Not available.

Long term exposure

Potential immediate effects Not available.

Potential delayed effects Not available.

Potential chronic health effects

Not available.

Conclusion/Summary Not available.

General No known significant effects or critical hazards.

Carcinogenicity No known significant effects or critical hazards.

Mutagenicity No known significant effects or critical hazards.

Teratogenicity No known significant effects or critical hazards.

Developmental effects No known significant effects or critical hazards.

Fertility effects No known significant effects or critical hazards.

Other information Not available.

SECTION 12: Ecological information**12.1 Toxicity**

Conclusion/Summary Not available.

12.2 Persistence and degradability

Conclusion/Summary Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Soil/water partition coefficient (K_{oc}) Not available.

Mobility Not available.

12.5 Results of PBT and vPvB assessment

This mixture does not contain any substances that are assessed to be a PBT or a vPvB.

12.6 Other adverse effects No known significant effects or critical hazards.

SECTION 13: Disposal considerations

The information in this section contains generic advice and guidance. The list of Identified Uses in Section 1 should be consulted for any available use-specific information provided in the Exposure Scenario(s).

13.1 Waste treatment methods

Product

Methods of disposal The generation of waste should be avoided or minimised wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction.

Hazardous waste Within the present knowledge of the supplier, this product is not regarded as hazardous waste, as defined by EU Directive 2008/98/EC.

Packaging

Methods of disposal The generation of waste should be avoided or minimised wherever possible. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible.

Special precautions This material and its container must be disposed of in a safe way. Empty containers or liners may retain some product residues. Avoid dispersal of spilt material and runoff and contact with soil, waterways, drains and sewers.

SECTION 14: Transport information

	ADR/RID	ADN	IMDG	IATA
14.1 UN number	Not available.	Not available.	Not available.	Not available.
14.2 UN proper shipping name	Not available.	Not available.	Not available.	Not available.
14.3 Transport hazard class(es)	Not available.	Not available.	Not available.	Not available.
14.4 Packing group	-	-	-	-
14.5 Environmental hazards	No.	No.	No.	No.
Additional information	-	-	-	-

14.6 Special precautions for user **Transport within user's premises:** always transport in closed containers that are upright and secure. Ensure that persons transporting the product know what to do in the event of an accident or spillage.

14.7 Transport in bulk according to IMO instruments Not available.

SECTION 15: Regulatory information

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

EU Regulation (EC) No. 1907/2006 (REACH)

Annex XIV - List of substances subject to authorisation

Annex XIV

None of the components are listed.

Substances of very high concern

None of the components are listed.

Annex XVII - Restrictions on the manufacture, placing on the market and use of certain dangerous substances, mixtures and articles Not applicable.

Other EU regulations

**Industrial emissions
(integrated pollution
prevention and control) - Air** Not listed

**Industrial emissions
(integrated pollution
prevention and control) -
Water** Not listed

Ozone depleting substances (1005/2009/EU)

Not listed.

Prior Informed Consent (PIC) (649/2012/EU)

Not listed.

Persistent Organic Pollutants

Not listed.

Seveso Directive

This product is not controlled under the Seveso Directive.

International regulations

Chemical Weapon Convention List Schedules I, II & III Chemicals

Not listed.

Montreal Protocol

Not listed.

Stockholm Convention on Persistent Organic Pollutants

Not listed.

Rotterdam Convention on Prior Informed Consent (PIC)

Not listed.

UNECE Aarhus Protocol on POPs and Heavy Metals

Not listed.

Inventory list

Europe All components are listed or exempted.

United States Not determined.

Canada inventory Not determined.


China All components are listed or exempted.

Japan **Japan inventory (CSCL):** Not determined.
Japan inventory (ISHL): Not determined.

**15.2 Chemical safety
assessment**

This product contains substances for which Chemical Safety Assessments are still required.

SECTION 16: Other information

 Indicates information that has changed from previously issued version.

Abbreviations and acronyms

ATE = Acute Toxicity Estimate
CLP = Classification, Labelling and Packaging Regulation [Regulation (EC) No. 1272/2008]
DMEL = Derived Minimal Effect Level
DNEL = Derived No Effect Level
EUH statement = CLP-specific Hazard statement
N/A = Not available
PBT = Persistent, Bioaccumulative and Toxic
PNEC = Predicted No Effect Concentration
RRN = REACH Registration Number
vPvB = Very Persistent and Very Bioaccumulative

Procedure used to derive the classification according to Regulation (EC) No. 1272/2008 [CLP/GHS]

Classification	Justification
Not classified.	

Full text of abbreviated H statements Not applicable.

Full text of classifications [CLP/ GHS] Not applicable.

Date of printing 05 July 2022

Date of issue/ Date of revision 05 July 2022

Date of previous issue 27 August 2019

Version 3

Notice to reader

To the best of our knowledge, the information contained herein is accurate. However, neither the above-named supplier, nor any of its subsidiaries, assumes any liability whatsoever for the accuracy or completeness of the information contained herein. Final determination of suitability of any material is the sole responsibility of the user. All materials may present unknown hazards and should be used with caution. Although certain hazards are described herein, we cannot guarantee that these are the only hazards that exist.
