

Amphotericin B

Safety Data Sheet

according to Regulation (EU) 2015/830

Date of issue: 30/11/2010 Revision date: 11/10/2017

Supersedes 24/01/2012

A0103

Version: 2.0

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

1.1. Product identifier

Product form : Substance
 Trade name : Amphotericin B
 EC-No. : 215-742-2
 CAS-No. : 1397-89-3
 Product code : A0103
 Formula : C₄₇H₇₃NO₁₇

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

1.2.1. Relevant identified uses

Main use category : Professional use
 Industrial/Professional use spec : For professional use only. Duchefa Biochemie B.V. products are intended only for "in vitro laboratory" research purposes.

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Duchefa Biochemie B.V.
 A. Hofmanweg 71
 2031 BH Haarlem - The Netherlands
 T +31(0)23-5319093 - F +31(0)23-5318027
info@duchefa.nl

1.4. Emergency telephone number

Emergency number : Supplier contact information:
 +31(0)23-5319093 (M-F 09:00-17:00)
 +31(0)6-30109355 (outside office hours)

Organisation/Company	Address	Comment
World Health Organization world directory of poison centres	http://apps.who.int/poisoncentres/	Consult website for a local poison centre

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Serious eye damage/eye irritation, Category 2 H319
 Skin corrosion/irritation, Category 2 H315
 Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation H335

Full text of hazard classes and H-statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

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

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Warning

Hazard statements (CLP) :

H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.

Precautionary statements (CLP) :

P280 - Wear protective gloves, protective clothing, face protection, eye protection.
P302+P352 - IF ON SKIN: Wash with plenty of water.
P305+P351 - IF IN EYES: Rinse cautiously with water for several minutes.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Comments : Content: 750 µg/mg
Name : Amphotericin B
CAS-No. : 1397-89-3
EC-No. : 215-742-2

Name	Product identifier	%
Amphotericin B	(CAS-No.) 1397-89-3 (EC-No.) 215-742-2	~ 100

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures after inhalation : Assure fresh air breathing. Get medical advice/attention.
First-aid measures after skin contact : After contact with skin, take off immediately all contaminated clothing, and wash immediately with plenty of water. Seek medical attention if ill effect or irritation develops.
First-aid measures after eye contact : In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
First-aid measures after ingestion : Rinse mouth out with water. If you feel unwell, seek medical advice.

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

No additional information available

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : Water. Dry chemical powder, alcohol-resistant foam, carbon dioxide (CO₂).

5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Under fire conditions, hazardous fumes will be present. CO_x. NO_x.

5.3. Advice for firefighters

Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection.

Other information : Prevent fire fighting water from entering the environment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Wear suitable protective clothing.

Measures in case of dust release : Avoid dust formation.

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Do not allow product to spread into the environment.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Sweep up dry powder and dispose properly.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Minimize generation of dust. Ensure good ventilation of the work station.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, cool, well-ventilated area. Protect from sunlight.

Storage temperature : 2 - 8 °C

7.3. Specific end use(s)

For professional use only. Duchefa Biochemie B.V. products are intended only for "in vitro laboratory" research purposes.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

No additional information available

8.2. Exposure controls

Hand protection:

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Type	Material	Permeation	Thickness (mm)	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11	EN 374

Eye protection:

Safety glasses

Skin and body protection:

Wear suitable protective clothing

Respiratory protection:

Filter type P3 (EN 143)

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Powder.
Molecular mass	: 924,1 g/mol
Colour	: Yellow.
Odour	: Characteristic.
Odour threshold	: No data available
pH	: No data available
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: > 170 °C
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: No data available
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

No additional information available

10.2. Chemical stability

Stable under normal conditions. May decompose under the influence of light.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

Light (daylight). Water, humidity.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

NOx. Carbon oxides (CO, CO2).

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Not classified

Amphotericin B (1397-89-3)	
LD50 oral rat	> 5000 mg/kg

Skin corrosion/irritation : Causes skin irritation.

Serious eye damage/irritation : Causes serious eye irritation.

Respiratory or skin sensitisation : Not classified

Germ cell mutagenicity : Not classified

Carcinogenicity : Not classified

Reproductive toxicity : Not classified

STOT-single exposure : May cause respiratory irritation.

STOT-repeated exposure : Not classified

Aspiration hazard : Not classified

SECTION 12: Ecological information

12.1. Toxicity

No additional information available

12.2. Persistence and degradability

No additional information available

12.3. Bioaccumulative potential

No additional information available

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

No additional information available

SECTION 13: Disposal considerations**13.1. Waste treatment methods**

Waste treatment methods : Dispose in a safe manner in accordance with local/national regulations. Avoid release to the environment.

SECTION 14: Transport information

In accordance with ADR / IATA / IMDG

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

14.6. Special precautions for user**. Overland transport**

Not applicable

- Transport by sea

Not applicable

- Air transport

Not applicable

14.7. Transport in bulk according to Annex II of Marpol and the IBC Code

Not applicable

SECTION 15: Regulatory information**15.1. Safety, health and environmental regulations/legislation specific for the substance or mixture****15.1.1. EU-Regulations**

No REACH Annex XVII restrictions

Amphotericin B is not on the REACH Candidate List

Amphotericin B is not on the REACH Annex XIV List

15.1.2. National regulations**Germany**

VwVwS Annex reference : Water hazard class (WGK) 3, severe hazard to waters (Classification according to VwVwS, Annex 1 or 2; ID No. 981)

12th Ordinance Implementing the Federal Immission Control Act - 12.BImSchV : Is not subject of the 12. BImSchV (Hazardous Incident Ordinance)

Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed

SZW-lijst van mutagene stoffen : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid : The substance is not listed

NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling : The substance is not listed

Denmark

Recommendations Danish Regulation : Young people below the age of 18 years are not allowed to use the product

15.2. Chemical safety assessment

No additional information available

SECTION 16: Other information

Indication of changes:

1.4	Emergency number	Modified	
2	Classification according to Directive 67/548/EEC [DSD] or 1999/45/EC [DPD]	Removed	Obsolete
8.2	Respiratory protection	Modified	P2 to P3
8.2	Hand protection	Modified	Specified material, thickness, et cetera of gloves

Abbreviations and acronyms:

ATE	Acute Toxicity Estimate
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
BCF	Bioconcentration factor
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008
DPD	Dangerous Preparations Directive 1999/45/EC
DSD	Dangerous Substances Directive 67/548/EEC
IATA	International Air Transport Association
IMDG	International Maritime Dangerous Goods
LC50	Median lethal concentration
LD50	Median lethal dose
LOAEL	Lowest Observed Adverse Effect Level
NOAEC	No-Observed Adverse Effect Concentration
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
SDS	Safety Data Sheet

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Data sources : Supplier. ECHA (European Chemicals Agency). REGULATION (EC) No 1272/2008 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 December 2008 on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006.

Full text of H- and EUH-statements:

Eye Irrit. 2	Serious eye damage/eye irritation, Category 2
Skin Irrit. 2	Skin corrosion/irritation, Category 2
STOT SE 3	Specific target organ toxicity — Single exposure, Category 3, Respiratory tract irritation
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H335	May cause respiratory irritation.

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This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product