

Amphotericin B

Safety Data Sheet

572020

Version: 3.1

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830
 Date of issue: 11/01/2012 Revision date 06/03/2020
 Supersedes 09/07/2018

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

1.1. Product identifier

Product form : Substance
 Substance name : Amphotericin B
 EC-No. : 215-742-2
 CAS-No. : 1397-89-3
 Product code : 572020
 Type of product : Antibiotics
 Formula : C₄₇H₇₃NO₁₇
 Product group : Raw material

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

1.2.1. Relevant identified uses

Main use category : Pharmaceutical
 Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals
 Function or use category : Raw material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Supplier

Duchefa Farma BV
 A. Hofmanweg 71
 2031BH Haarlem - The Netherlands
 T +31(0)23-5319093
farma@ducheffa.nl - www.duchefa-farma.com

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
Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Acute toxicity (dermal), Category 4

H312

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Acute toxicity (inhalation:dust,mist) Category 4 H332
Skin corrosion/irritation, Category 2 H315
Serious eye damage/eye irritation, Category 2 H319
Specific target organ toxicity — Single exposure, Category 3, H335
Respiratory tract irritation

Full text of 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] Extra labelling to display Extra classification(s) to display

Hazard pictograms (CLP) :



GHS07

Signal word (CLP) :

Warning

Hazard statements (CLP) :

H312+H332 - Harmful in contact with skin or if inhaled
H315 - Causes skin irritation.
H319 - Causes serious eye irritation.
H335 - May cause respiratory irritation.

Precautionary statements (CLP) :

P280 - Wear eye protection, face protection, protective clothing, protective gloves.
P302+P352 - IF ON SKIN: Wash with plenty of water/...
P305+P351 - IF IN EYES: Rinse cautiously with water for several minutes.
P304+P340 - IF INHALED: Remove person to fresh air and keep comfortable for breathing.

2.3. Other hazards

Other hazards not contributing to the classification : No additional information available.

SECTION 3: Composition/information on ingredients

3.1. Substances

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Amphotericin B	(CAS-No.) 1397-89-3 (EC-No.) 215-742-2	100	Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation:dust,mist) , H332 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

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 general	: If medical advice is needed, have product container or label at hand.
First-aid measures after inhalation	: Remove victim to fresh air Seek medical advice. If not breathing, give artificial respiration.
First-aid measures after skin contact	: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse Seek medical attention if ill effect or irritation develops.
First-aid measures after eye contact	: Rinse immediately with plenty of water.
First-aid measures after ingestion	: Rinse mouth. Get medical advice/attention.

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 spray dry chemical powder, alcohol-resistant foam, carbon dioxide (CO ₂).
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5.2. Special hazards arising from the substance or mixture

Fire hazard	: On exposure to high temperature, may decompose, releasing toxic gases. Carbon monoxide. Nitrogen oxides.
Explosion hazard	: Product is not explosive.

5.3. Advice for firefighters

Firefighting instructions	: Prevent fire fighting water from entering the environment.
Protection during firefighting	: Do not enter fire area without proper protective equipment, including respiratory protection.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

General measures	: Eliminate every possible source of ignition. Evacuate area. Avoid raising dust.
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6.1.1. For non-emergency personnel

No additional information available

6.1.2. For emergency responders

No additional information available

6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

For containment : Sweeping or shovelling without dust for disposal.

Methods for cleaning up : Hose down area with water.

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 : Do not get in eyes, on skin, or on clothing. Wear personal protective equipment. Avoid raising dust. Ensure good ventilation of the work station.

Hygiene measures : Handle in accordance with good industrial hygiene and safety practice.

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)

Pharmaceutical industry.

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

No additional information available

8.2. Exposure controls**Appropriate engineering controls:**

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

Hand protection:

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

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

Approved dust respirator. Dustmask with filtertype P3

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	: Insoluble in water.
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.

10.3. Possibility of hazardous reactions

No additional information available

10.4. Conditions to avoid

Water, humidity
Air contact
High temperature.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Carbon dioxide
Carbon monoxide
Nitrogen oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Harmful in contact with skin. Harmful if inhaled.

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 : Avoid release to the environment.

Product/Packaging disposal : Dispose in a safe manner in accordance with local/national recommendations regulations.

SECTION 14: Transport information

In accordance with ADR / RID / IMDG / IATA / ADN

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

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

No data available

- Air transport

No data available

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**

Reference to AwSV

: Water hazard class (WGK) 3, Highly hazardous to water (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
Pregnant/breastfeeding women working with the product must not be in direct contact with the product

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

	Type of product	Added	
		Modified	change of logo

Abbreviations and acronyms:

ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
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
EC50	Median effective concentration
IARC	International Agency for Research on Cancer
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
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
PBT	Persistent Bioaccumulative Toxic
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail

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SDS	Safety Data Sheet
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Data sources : EP. Supplier.

Full text of H- and EUH-statements:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
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
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H319	Causes serious eye irritation.
H332	Harmful if inhaled.
H335	May cause respiratory irritation.

SDS EU (REACH Annex II) duchefa nieuwe logo

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.