

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Reference number: A0103

Issue date: 05/02/2025 Revision date: 04/02/2025 Supersedes version of: 11/10/2017 Version: 3.0

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 (Override) : $C_{47}H_{73}NO_{17}$
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 : 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

Supplier

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)6-30008100 (outside office hours)

Country	Organisation/Company	Address	Emergency number	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]

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

Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

May cause respiratory irritation. Causes skin irritation. Causes serious eye irritation.

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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) :

P261 - Avoid breathing dust.
P264 - Wash hands thoroughly after handling.
P280 - Wear protective clothing, eye protection, face protection.
P312 - Call a POISON CENTRE or doctor if you feel unwell.
P337+P313 - If eye irritation persists: Get medical advice/attention.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Comments : Content: \geq 750 IU/mg

Substance type : Mono-constituent

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

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general : Call a poison center or a doctor if you feel unwell.
First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. Call a poison center or a doctor if you feel unwell.
First-aid measures after skin contact : Wash skin with plenty of water. Take off contaminated clothing. If skin irritation occurs: Get medical advice/attention.
First-aid measures after eye contact : Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists: Get medical advice/attention.
First-aid measures after ingestion : Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects after inhalation : May cause respiratory irritation.
Symptoms/effects after skin contact : Irritation.
Symptoms/effects after eye contact : Eye irritation.
Symptoms/effects after ingestion : None under normal conditions.

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

Treat symptomatically.

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SECTION 5: Firefighting measures

5.1. Extinguishing media

- Suitable extinguishing media : Dry chemical powder, alcohol-resistant foam, carbon dioxide (CO₂). Water spray.
- Unsuitable extinguishing media : Do not use a heavy water stream.

5.2. Special hazards arising from the substance or mixture

- Fire hazard : No fire hazard.
- Explosion hazard : No direct explosion hazard.
- Hazardous decomposition products in case of fire : - CO_x. - NO_x.

5.3. Advice for firefighters

- Firefighting instructions : Fight fire from safe distance and protected location. Do not enter fire area without proper protective equipment, including respiratory protection.
- Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection. Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.
- Other information : Prevent fire fighting water from entering the environment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

- General measures : Notify authorities if product enters sewers or public waters. Absorb spillage to prevent material damage.

6.1.1. For non-emergency personnel

- Protective equipment : Wear suitable protective clothing.
- Emergency procedures : Ventilate spillage area. Avoid breathing dust. Avoid contact with skin and eyes.
- Measures in case of dust release : Avoid dust formation.

6.1.2. For emergency responders

- Protective equipment : Do not attempt to take action without suitable protective equipment. For further information refer to section 8: "Exposure controls/personal protection".
- Emergency procedures : Evacuate unnecessary personnel.

6.2. Environmental precautions

Avoid release to the environment. Do not allow product to spread into the environment.

6.3. Methods and material for containment and cleaning up

- For containment : Using a clean shovel, put the material in a dry container and cover without compressing it.
- Methods for cleaning up : Mechanically recover the product. Sweep up dry powder and dispose properly.
- Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 8.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

- Additional hazards when processed : Not expected to present a significant hazard under anticipated conditions of normal use.
- Precautions for safe handling : Minimise generation of dust. Ensure good ventilation of the work station. Use only outdoors or in a well-ventilated area. Avoid breathing dust. Avoid contact with skin and eyes. Wear personal protective equipment.

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Hygiene measures : Wash contaminated clothing before reuse. Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Technical measures : Keep in a cool, well-ventilated place away from heat.
 Storage conditions : Protect from sunlight. Store in a well-ventilated place. Keep container tightly closed.
 Storage temperature : 2 – 8 °C
 Packaging materials : Store always product in container of same material as original container.

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

8.1.1 National occupational exposure and biological limit values

No additional information available

8.1.2. Recommended monitoring procedures

No additional information available

8.1.3. Air contaminants formed

No additional information available

8.1.4. DNEL and PNEC

No additional information available

8.1.5. Control banding

No additional information available

8.2. Exposure controls

8.2.1. Appropriate engineering controls

Appropriate engineering controls:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment:

Wear recommended personal protective equipment.

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection			
Type	Field of application	Characteristics	Standard
Safety glasses	Dust		EN 166

8.2.2.2. Skin protection

Skin and body protection:

Wear suitable protective clothing

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

8.2.2.3. Respiratory protection

Respiratory protection			
Device	Filter type	Condition	Standard
Dust mask	Type P3	Dust protection	EN 143

8.2.2.4. Thermal hazards

No additional information available

8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: Yellow. Orange.
Appearance	: Powder.
Molecular mass	: 924,1 g/mol
Odour	: Characteristic.
Odour threshold	: Not available
Melting point	: > 170 °C
Freezing point	: Not applicable
Boiling point	: Not available
Flammability	: Non flammable.
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: Not available
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Practically insoluble in : Water.
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: Not applicable
Particle size	: Not available

9.2. Other information

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. Other safety characteristics

No additional information available

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SECTION 10: Stability and reactivity

10.1. Reactivity

The product is non-reactive under normal conditions of use, storage and transport.

10.2. Chemical stability

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

10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

10.4. Conditions to avoid

Light (daylight). Water, humidity.

10.5. Incompatible materials

No additional information available

10.6. Hazardous decomposition products

- NO_x. - CO_x.

SECTION 11: Toxicological information

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

Acute toxicity (oral) : Not classified
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

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LD50 oral rat	> 5000 mg/kg
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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

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Viscosity, kinematic	Not applicable
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11.2. Information on other hazards

11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The substance/mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %

11.2.2. Other information

No additional information available

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SECTION 12: Ecological information

12.1. Toxicity

- Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
- Hazardous to the aquatic environment, short-term (acute) : Not classified
- Hazardous to the aquatic environment, long-term (chronic) : Not classified

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. Endocrine disrupting properties

- Adverse effects on the environment caused by endocrine disrupting properties : The substance/mixture does not contain substance(s) included in the list established in accordance with Article 59(1) of REACH for having endocrine disrupting properties, or is not identified as having endocrine disrupting properties in accordance with the criteria set out in Commission Delegated Regulation (EU) 2017/2100 or Commission Regulation (EU) 2018/605 at a concentration equal to or greater than 0,1 %.

12.7. Other adverse effects

No additional information available

SECTION 13: Disposal considerations

13.1. Waste treatment methods

- Regional waste regulation : Disposal must be done according to official regulations.
- Waste treatment methods : Dispose in a safe manner in accordance with local/national regulations. Avoid release to the environment. Dispose of contents/container in accordance with licensed collector's sorting instructions.
- Sewage disposal recommendations : Disposal must be done according to official regulations.
- Product/Packaging disposal recommendations : Comply with applicable regulations for solid waste disposal. Disposal must be done according to official regulations.
- Additional information : Do not re-use empty containers.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
Not applicable	Not applicable	Not applicable
14.2. UN proper shipping name		
Not applicable	Not applicable	Not applicable

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ADR	IMDG	IATA
14.3. Transport hazard class(es)		
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. Maritime transport in bulk according to IMO instruments

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****REACH Annex XVII (Restriction List)**

Not listed on REACH Annex XVII

REACH Annex XIV (Authorisation List)

Not listed on REACH Annex XIV (Authorisation List)

REACH Candidate List (SVHC)

Contains no substance(s) listed on the REACH Candidate List

PIC Regulation (Prior Informed Consent)

Not listed on the PIC list (Regulation EU 649/2012)

POP Regulation (Persistent Organic Pollutants)

Not listed on the POP list (Regulation EU 2019/1021)

Ozone Regulation (1005/2009)

Not listed on the Ozone Depletion list (Regulation EU 2024/590)

Explosives Precursors Regulation (2019/1148)

Contains no substance(s) listed on the Explosives Precursors list (Regulation EU 2019/1148 on the marketing and use of explosives precursors)

Drug Precursors Regulation (273/2004)

Contains no substance(s) listed on the Drug Precursors list (Regulation EC 273/2004 on the manufacture and the placing on market of certain substances used in the illicit manufacture of narcotic drugs and psychotropic substances)

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15.1.2. National regulations

Germany

Water hazard class (WGK) : WGK 3, Highly hazardous to water (Classification according to AwSV).
 Hazardous Incident Ordinance (12. BImSchV) : Is not subject to the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed
 SZW-lijst van mutagene stoffen : The substance is not listed
 SZW-lijst van reprotoxische stoffen – Borstvoeding : The substance is not listed
 SZW-lijst van reprotoxische stoffen – Vruchtbaarheid : The substance is not listed
 SZW-lijst van reprotoxische stoffen – Ontwikkeling : The substance is not listed

Denmark

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

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	Substance type	Added	
	Adverse health effects caused by endocrine disrupting properties	Added	
	Comments (on top of composition)	Modified	
1.1	Product group	Added	
1.1	Formula	Modified	
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
2.1	Adverse physicochemical, human health and environmental effects	Added	
2.2	Precautionary statements (CLP)	Modified	
3	Composition/information on ingredients	Modified	
4.1	First-aid measures for first aider	Added	
4.1	First-aid measures general	Added	
4.1	First-aid measures after skin contact	Modified	
4.1	First-aid measures after inhalation	Modified	
4.1	First-aid measures after ingestion	Modified	
4.1	First-aid measures after eye contact	Modified	
4.2	Symptoms/effects after ingestion	Added	
4.2	Symptoms/effects after eye contact	Added	
4.2	Symptoms/effects after skin contact	Added	
4.2	Symptoms/effects after inhalation	Added	

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Indication of changes			
Section	Changed item	Change	Comments
4.3	Other medical advice or treatment	Added	
5.1	Unsuitable extinguishing media	Added	
5.1	Suitable extinguishing media	Modified	
5.2	Hazardous decomposition products in case of fire	Modified	
5.2	Fire hazard	Added	
5.2	Explosion hazard	Added	
5.3	Firefighting instructions	Added	
5.3	Protection during firefighting	Modified	
6.1	Emergency procedures	Added	
6.1	Protective equipment	Added	
6.1	Emergency procedures	Added	
6.1	General measures	Added	
6.2	Environmental precautions	Modified	
6.3	For containment	Added	
6.3	Other information	Added	
6.3	Methods for cleaning up	Modified	
6.4	Reference to other sections (8, 13)	Added	
7.1	Precautions for safe handling	Modified	
7.1	Additional hazards when processed	Added	
7.1	Hygiene measures	Added	
7.2	Storage conditions	Modified	
7.2	Technical measures	Added	
7.2	Packaging materials	Added	
8	Formula	Modified	
8.2	Respiratory protection	Removed	
8.2	Eye protection	Removed	
8.2	Environmental exposure controls	Added	
8.2	Personal protective equipment	Added	
8.2	Appropriate engineering controls	Added	
9	Solubility	Added	
9	Colour	Modified	
9	Flammability	Added	
9	Viscosity, kinematic	Added	
9	Freezing point	Added	
9	Flash point	Added	
9	Auto-ignition temperature	Added	

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Indication of changes			
Section	Changed item	Change	Comments
9.1	Explosive limits (vol %)	Added	
10.1	Reactivity	Added	
10.3	Possibility of hazardous reactions	Added	
10.6	Hazardous decomposition products	Modified	
12.1	Ecology - general	Added	
12.6	Adverse effects on the environment caused by endocrine disrupting properties	Added	
13.1	Product/Packaging disposal recommendations	Added	
13.1	Sewage disposal recommendations	Added	
13.1	Additional information	Added	
13.1	Regional waste regulation	Added	
13.1	Waste treatment methods	Modified	
15.2	Chemical safety assessment	Added	
16	Other information	Added	
16	Data sources	Modified	
16	Abbreviations and acronyms	Modified	

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
ACGIH	American Conference of Government Industrial Hygienists
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
BLV	Biological limit value

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Abbreviations and acronyms:	
BOD	Biochemical oxygen demand (BOD)
CAS-No.	Chemical Abstract Service number
COD	Chemical oxygen demand (COD)
CSA	Chemical safety assessment
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level
EC-No.	European Community number
EC50	Median effective concentration
ED	Endocrine disruptor
EN	European Standard
EWC	European waste catalogue
IARC	International Agency for Research on Cancer
Log Kow	Partition coefficient n-octanol/water (Log Kow)
Log Pow	Partition coefficient n-octanol/water (Log Pow)
MAK	maximum workplace concentration
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
N.O.S.	Not Otherwise Specified
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
OSHA	Occupational Safety Health Administration
PNEC	Predicted No-Effect Concentration
PPE	Personal protection equipment
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
STP	Sewage treatment plant
TF	Technical function
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
TWA	Time Weighted Average
VOC	Volatile Organic Compounds
vPvB	Very Persistent and Very Bioaccumulative
UFI	Unique Formula Identifier

Data sources

: Supplier's safety documents. 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.

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Other information

: **DISCLAIMER OF LIABILITY** The information in this SDS was obtained from sources which we believe are reliable. However, the information is provided without any warranty, express or implied, regarding its correctness.

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.

Safety Data Sheet (SDS), EU Duchefa 2023

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.