

# Amphotericin B suspension

## Safety Data Sheet

**A0192**

according to Regulation (EU) 2015/830

Version: 2.1

Date of issue: 03/04/2012      Revision date 23/01/2019  
Supersedes 25/10/2017

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

#### 1.1. Product identifier

Product form : Mixture  
Trade name : Amphotericin B suspension  
Product code : A0192

#### 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](mailto: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	<a href="http://apps.who.int/poisoncentres/">http://apps.who.int/poisoncentres/</a>	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]

Not classified

##### Adverse physicochemical, human health and environmental effects

No additional information available

#### 2.2. Label elements

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

No labelling applicable

#### 2.3. Other hazards

No additional information available

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Not applicable

### 3.2. Mixtures

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Additives		<= 90	Not classified
Amphotericin B	(CAS-No.) 1397-89-3 (EC-No.) 215-742-2	<= 10	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Skin Irrit. 2, H315 Eye Irrit. 2, H319 STOT SE 3, H335

Full text of H-statements: see section 16

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

- First-aid measures general : Seek medical attention if ill effect or irritation develops.
- First-aid measures after inhalation : Assure fresh air breathing.
- 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.
- First-aid measures after eye contact : Rinse with water  
Seek medical attention if ill effect or irritation develops.
- First-aid measures after ingestion : Rinse mouth.

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

- Symptoms/effects after inhalation : May cause irritation to the respiratory tract, sneezing, coughing, burning sensation of throat with constricting sensation of the larynx and difficulty in breathing.
- Symptoms/effects after skin contact : May cause skin irritation.
- Symptoms/effects after eye contact : May cause eye irritation.
- Symptoms/effects after ingestion : May cause irritation to the digestive tract.

### 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<sub>2</sub>).

### 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:  
- COx  
- NOx.

### 5.3. Advice for firefighters

Protection during firefighting : Wear recommended personal protective equipment.

## SECTION 6: Accidental release measures

### 6.1. Personal precautions, protective equipment and emergency procedures

#### 6.1.1. For non-emergency personnel

Protective equipment : Wear recommended personal protective equipment.

#### 6.1.2. For emergency responders

No additional information available

### 6.2. Environmental precautions

Avoid release to the environment. Do not allow to enter drains or water courses.

### 6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Collect spillage.

### 6.4. Reference to other sections

No additional information available

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Additional hazards when processed : Handle in accordance with good industrial hygiene and safety procedures.

### 7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area  
Store at room temperature  
Protect from sunlight.

### 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:

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 P1 (EN 143)

## SECTION 9: Physical and chemical properties

### 9.1. Information on basic physical and chemical properties

Physical state	: Liquid
Appearance	: Viscous liquid.
Molecular mass	: 924,1 g/mol
Colour	:
Odour	: Citrus fruits.
Odour threshold	: No data available
pH	: 5,3 - 5,8
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: > 100 °C
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	: 1,05 (≥ 1,09)
Solubility	: In water, material is partially soluble.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: > 200 mPa·s 25°C
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

- Heat.

### 10.5. Incompatible materials

No additional information available

### 10.6. Hazardous decomposition products

When heated to decomposition, emits dangerous fumes:

- CO<sub>x</sub>
- NO<sub>x</sub>.

## SECTION 11: Toxicological information

### 11.1. Information on toxicological effects

Acute toxicity	: Not classified
Skin corrosion/irritation	: Not classified pH: 5,3 - 5,8
Serious eye damage/irritation	: Not classified pH: 5,3 - 5,8
Respiratory or skin sensitisation	: Not classified
Germ cell mutagenicity	: Not classified
Carcinogenicity	: Not classified
Reproductive toxicity	: Not classified
STOT-single exposure	: Not classified
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

Additional information : Prevent entry to sewers and public waters. Avoid release to the environment

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

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

**SECTION 14: Transport information**

In accordance with ADR / IATA / IMDG

ADR	IMDG	IATA
<b>14.1. UN number</b>		
Not applicable	Not applicable	Not applicable
<b>14.2. UN proper shipping name</b>		
Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable
<b>14.3. Transport hazard class(es)</b>		
Not applicable	Not applicable	Not applicable
Not applicable	Not applicable	Not applicable
<b>14.4. Packing group</b>		
Not applicable	Not applicable	Not applicable
<b>14.5. Environmental hazards</b>		
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**

Contains no REACH substances with Annex XVII restrictions

Contains no substance on the REACH candidate list

Contains no REACH Annex XIV substances

**15.1.2. National regulations**

Ensure all national/local regulations are observed.

**Germany**

Reference to AwSV

: Water hazard class (WGK) 3, Highly hazardous to water (Classification according to AwSV, Annex 1)

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

: None of the components are listed

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SZW-lijst van mutagene stoffen	: None of the components are listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Borstvoeding	: None of the components are listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Vruchtbaarheid	: None of the components are listed
NIET-limitatieve lijst van voor de voortplanting giftige stoffen – Ontwikkeling	: None of the components are listed

### Denmark

Recommendations Danish Regulation	: Pregnant/breastfeeding women working with the product must not be in direct contact with the product
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### 15.2. Chemical safety assessment

No additional information available

## SECTION 16: Other information

Indication of changes:

1.2	Added	Added missing information in section 1.2
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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

Data sources : ECHA (European Chemicals Agency). Supplier. 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:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal), Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral), 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
H302	Harmful if swallowed.
H312	Harmful in contact with skin.
H315	Causes skin irritation.
H319	Causes serious eye irritation.

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H335	May cause respiratory irritation.
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SDS Biochemicals version 2019

*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*