

# AMCIPATRICIN

## Safety Data Sheet

SDS EU format according to COMMISSION REGULATION (EU) 2020/878

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

#### 1.1. Product identifier

|                        |   |
|------------------------|---|
| Product form           | : Mono constituent substance  |
| Trade name             | : Amcipatricin  |
| IUPAC name             | : N – Dimethylaminoacetyl Partricin A, 2 – Dimethylamminoethylamide |
| EC-No.                 | : Not available   |
| CAS-No.                | : 143483-67-4   |
| REACH registration No. | : Not applicable  |
| Formula                | : C <sub>67</sub> H <sub>103</sub> N <sub>5</sub> O <sub>19</sub>   |
| Synonyms               | : SPA-S-752   |

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

##### 1.2.1. Relevant identified uses

Use of the substance/mixture : R&D use only; Laboratory chemicals.

##### 1.2.2. Uses advised against

Restrictions on use : Contact supplier for more information on uses.

#### 1.3. Details of the supplier of the safety data sheet

Fordras SA, A Bioseutica Group Company  
Corso Elvezia 4, CH-6900 Lugano, Switzerland  
Phone: +41 (0) 91 9119036 - Fax: +41 (0) 91 9119037  
[info-fordras@bioseutica.com](mailto:info-fordras@bioseutica.com)

#### 1.4. Emergency telephone number

Emergency number : QESH Manager Bioseutica BV  
+31-(0)36- 5234059 (business hours)  
+31-(0)6- 12376175 (24 hours)

### SECTION 2: Hazards identification

#### 2.1. Classification of the substance or mixture

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

Specific target organ toxicity repeated exposure, (Category 1) - H372: Causes damage to organs through prolonged or repeated exposure.

##### 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):



Signal Word (CLP):

Danger

Hazard statements (CLP):

H372- Causes damage to organs through prolonged or repeated exposure.

### Precautionary Statements (CLP):

- P260 - Do not breathe dust.
- P264 - Wash skin thoroughly after handling.
- P270 - Do not eat, drink or smoke when using this product.
- P314 - Get medical advice/ attention if you feel unwell
- P501 - Dispose of contents/ container to an approved waste disposal plant.

Supplemental Hazard Statements: none

### 2.3. Other hazards

This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII

This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII

The substance is not 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

## SECTION 3: Composition/information on ingredients

### 3.1. Substances

Substance type : Mono constituent substance

| Name          | Product identifier   | %    |
|---------------|----------------------|------|
| Ampicpatricin | CAS-No.: 143483-67-4 | ≥ 90 |

### 3.2. Mixtures

Not applicable

## SECTION 4: First aid measures

### 4.1. Description of first aid measures

- First-aid measures after inhalation : Remove person to fresh air and keep comfortable for breathing. If swallowed, wash out mouth with water provided person is conscious. Call a physician.
- First-aid measures after skin contact : flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. Call a physician.
- First-aid measures after eye contact : Immediately flush eyes thoroughly with water for at least 15 minutes. Remove contact lenses, if present and easy to do. Continue rinsing. Seek immediate medical advice.
- First-aid measures after ingestion : Rinse mouth out with water. Never give anything by mouth to an unconscious person. Do not induce vomiting. Seek immediate 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

Treat symptomatically.

## SECTION 5: Firefighting measures

### 5.1. Extinguishing media

Suitable extinguishing media : Carbon dioxide (CO<sub>2</sub>), dry chemical powder, foam. Water spray jet.

### 5.2. Special hazards arising from the substance or mixture

Hazardous decomposition products in case of fire : Toxic fumes may be released.

### 5.3. Advice for firefighters

Protective equipment for firefighters : Use a self-contained breathing apparatus and also a protective suit. Helmet. EN 469.  
Other information : Collect contaminated fire extinguishing water separately. This must not be discharged into drains. Fire residues and contaminated fire extinguishing water must be disposed of in accordance with local regulations.

## SECTION 6: Accidental release measures

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

General measures : Ensure adequate ventilation. Avoid generation of dust. Avoid breathing dust, mist or spray. Avoid contact with skin and eyes.

#### 6.1.1. For non-emergency personnel

Protective equipment : Do not attempt to take action without suitable protective equipment. Wear suitable protective clothing, gloves and eye or face protection. Wear personal protective equipment. Wear respiratory protection. Eye/face protection. Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses. Skin protection Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of Regulation (EU)2016/425 and the standard EN 374 derived from it.

Emergency procedures : Only qualified personnel equipped with suitable protective equipment may intervene.

#### 6.1.2. For emergency responders

Protective equipment : Wear recommended personal protective equipment. Do not enter fire area without proper protective equipment, including respiratory protection.  
Emergency procedures : Evacuate unnecessary personnel. In case of leakage, eliminate all ignition sources.

### 6.2. Environmental precautions

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

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

Methods for cleaning up : Wear recommended personal protective equipment. Ventilate area. Sweep up or vacuum up the product. Avoid dust formation. Collect all waste in suitable and labelled containers and dispose according to local legislation. Clean contaminated surfaces with an excess of water. Mechanically recover the product.

### 6.4. Reference to other sections

For further information refer to section 8: "Exposure controls/personal protection". For disposal of residues refer to section 13 : "Disposal considerations".

## SECTION 7: Handling and storage

### 7.1. Precautions for safe handling

Additional hazards when processed : Generation of airborne dust.  
Precautions for safe handling : Work under hood. Avoid dust formation. Avoid contact with skin, eyes and clothing.  
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product. Contaminated work clothing should not be allowed out of the workplace.

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

Technical measures : Use grounded electrical/mechanical equipment.  
Storage conditions : Store the product in well-closed dark glass vials, under nitrogen, at  $\leq +5^{\circ}\text{C}\pm 3^{\circ}\text{C}$  and protect from light. . Keep out of direct sunlight. Protect from moisture. Keep container tightly closed. Handle uncleaned empty containers as full ones.  
Heat and ignition sources : Keep away from open flames, hot surfaces and sources of ignition.

## SECTION 8: Exposure controls/personal protection

### 8.1. Control parameters

#### 8.1.1 National occupational exposure and biological limit values

No additional information available

#### 2. Recommended monitoring procedures

No additional information available

#### 3. Air contaminants formed

No additional information available

#### 4. DNEL and PNEC

No additional information available

#### 5. Control banding

No additional information available

### 8.2. Exposure controls

#### 1. Appropriate engineering controls

##### Appropriate engineering controls:

Provide adequate ventilation.

#### 2. Personal protection equipment

##### Personal protective equipment:

Safety glasses. Gloves. Wear a mask. Dust/aerosol mask with filter type P2.

##### Personal protective equipment symbol(s):



#### 1. Eye and face protection

##### Eye protection:

Use equipment for eye protection tested and approved under appropriate government standards such as NIOSH (US) or EN 166(EU). Safety glasses

#### 2. Skin protection

##### Skin and body protection:

Chemical resistant protective apron / clothing (tested to EN 14605 or equivalent).

##### Hand protection:

Handle with gloves. Gloves must be inspected prior to use. Use proper glove removal technique (without touching glove's outer surface) to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with applicable laws and good laboratory practices. Wash and dry hands. The selected protective gloves have to satisfy the specifications of Regulation (EU) 2016/425 and the standard EN 374 derived from it.

##### Other skin protection

##### Materials for protective clothing:

Wear suitable protective clothing

#### 3. Respiratory protection

##### Respiratory protection:

required when dusts are generated. Our recommendations on filtering respiratory protection are based on the following standards: DIN EN 143, DIN 14387 and other accompanying standards relating to the used respiratory protection system. Recommended Filter type: Filter type P3. The entrepreneur has to ensure that maintenance, cleaning and testing of respiratory protective devices are carried out according to the instructions of the producer. These measures have to be properly documented.

#### 4. Thermal hazards

No additional information available

#### 8.2.3. Environmental exposure controls

##### Environmental exposure controls:

Do not allow uncontrolled discharge of product into the environment. The final disposal of this material should be supervised by a specialist, following applicable environmental legislation.

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Handle in accordance with good industrial hygiene and safety procedures.

### SECTION 9: Physical and chemical properties

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

|   |  |
|---|--|
| Physical state                                  | : Solid  |
| Colour  | : Yellow   |
| Appearance                                      | : Powder   |
| Molecular mass                                  | : 1282,6 g/mol                                       |
| Odour   | : Almost odorless.                                   |
| Odour threshold                                 | : Not available                                      |
| Melting point                                   | : 208,4-211,6°C (DSC)                                |
| Freezing point                                  | : Not determined                                     |
| Boiling point                                   | : Not determined                                     |
| Flammability                                    | : Not flammable                                      |
| Explosive properties                            | : Not explosive.                                     |
| Oxidising properties                            | : Non oxidizing.                                     |
| Explosive limits                                | : Not applicable                                     |
| Lower explosion limit                           | : Not determined                                     |
| Upper explosion limit                           | : Not determined                                     |
| Flash point                                     | : Not applicable                                     |
| Auto-ignition temperature                       | : Not self-igniting                                  |
| Decomposition temperature                       | : Not determined                                     |
| pH  | : Not determined                                     |
| pH solution                                     | : Not available                                      |
| Viscosity, kinematic                            | : Not applicable                                     |
| Viscosity, dynamic                              | : Not applicable                                     |
| Solubility:                                     | : Soluble in dimethylformamide and dimethylsulfoxide |
| Partition coefficient n-octanol/water (Log Kow) | : Not available                                      |
| Partition coefficient n-octanol/water (Log Pow) | : Not available                                      |
| Vapour pressure                                 | : Not available                                      |
| Vapour pressure at 50°C                         | : Not determined                                     |
| Density   | : Not determined                                     |
| Relative density                                | : Not determined                                     |
| Relative vapour density at 20°C                 | : Not applicable                                     |
| Particle size                                   | : Not available                                      |

#### 9.2. Other information

##### 1. Information with regard to physical hazard classes

No additional information available

##### 2. Other safety characteristics

No additional information available

### SECTION 10: Stability and reactivity

#### 10.1. Reactivity

Stable under normal conditions of use.

#### 10.2. Chemical stability

Stable under normal conditions.

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### 10.3. Possibility of hazardous reactions

No dangerous reactions known under normal conditions of use.

### 10.4. Conditions to avoid

Moisture. Direct sunlight.

### 10.5. Incompatible materials

Avoid the contact with metallic surfaces

### 10.6. Hazardous decomposition products

No hazardous decomposition products under suitable storage and usage conditions as prescribed.

## 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

| Amcipatricin (143483-67-4) |              |
|----------------------------|--------------|
| LD50 oral rat              | > 2000 mg/kg |
| LD50 intravenous rat       | 29 mg/Kg     |
| LD50 oral mouse            | > 2000 mg/Kg |
| LD50 intravenous mouse     | 150 mg/kg    |
| LD50 intraperitoneal mouse | 188 mg/kg    |

Skin corrosion/irritation : Not classified  
Serious eye damage/irritation : Not classified  
Respiratory or skin sensitisation : Not classified  
Germ cell mutagenicity : Not classified  
Carcinogenicity : Not classified  
Reproductive toxicity : Not classified  
Additional information : Not classified  
STOT-single exposure : Not classified  
STOT-repeated exposure : Not classified  
Additional information : Not classified  
Aspiration hazard : Not classified

| Amcipatricin (143483-67-4) |                |
|----------------------------|----------------|
| Viscosity, kinematic       | Not applicable |

### 11.2. Information on other hazards

#### 11.2.1. Endocrine disrupting properties

Adverse health effects caused by endocrine disrupting properties : The substance is not 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

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### 11.2.2. Other information

Potential Adverse human health effects and symptoms

: Exposure by intravenous route can cause :  
Nausea, headache, vomiting, convulsions, chills, fever, malaise, muscle and joint pain, rash, anorexia, diarrhea, gastrointestinal cramps, hypertension, hypotension, cardiac arrhythmias, ventricular fibrillation, cardiac arrest, blurred vision, tinnitus, vertigo, anaemia and hypokalemia. Repeated or prolonged exposure could cause allergy reactions in sensitive subjects.  
- Affected organ(s) information: Kidneys  
- Chronic effects: Data not yet available  
- Target organs: Kidneys and liver.

## SECTION 12: Ecological information

### 12.1. Toxicity

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

| Amcipatricin (143483-67-4)    |                |
|-------------------------------|----------------|
| Persistence and degradability | Not determined |

### 12.3. Bioaccumulative potential

| Amcipatricin (143483-67-4)                      |                |
|---|----------------|
| Partition coefficient n-octanol/water (Log Pow) | Not available  |
| Bioaccumulative potential                       | Not available. |

### 12.4. Mobility in soil

| Amcipatricin (143483-67-4) |   |
|----------------------------|---|
| Mobility in soil           | The substance is expected not to evaporate from the water surface into the atmosphere, on the basis of its physical properties. |

### 12.5. Results of PBT and vPvB assessment

| Amcipatricin (143483-67-4)   |  |
|--|--|
| This substance/mixture does not meet the PBT criteria of REACH regulation, annex XIII  |  |
| This substance/mixture does not meet the vPvB criteria of REACH regulation, annex XIII |  |

### 12.6. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The substance is not 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.

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### 12.7. Other adverse effects

No additional information available

## SECTION 13: Disposal considerations

### 13.1. Waste treatment methods

Regional legislation (waste) : Disposal must be done according to the Directive 2008/98/CE. Dispose of in a safe manner in accordance with local/national regulations. Empty containers should be taken for recycling, recovery or waste in accordance with local regulation.

## SECTION 14: Transport information

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

| AD                                      | IMD           | IAT           | AD            | RID           |
|---|---------------|---------------|---------------|---------------|
| <b>14.1. UN number or ID number</b>     |               |               |               |               |
| Not regulated                           | Not regulated | Not regulated | Not regulated | Not regulated |
| <b>14.2. UN proper shipping name</b>    |               |               |               |               |
| Not regulated                           | Not regulated | Not regulated | Not regulated | Not regulated |
| <b>14.3. Transport hazard class(es)</b> |               |               |               |               |
| Not regulated                           | Not regulated | Not regulated | Not regulated | Not regulated |
| <b>14.4. Packing group</b>              |               |               |               |               |
| Not regulated                           | Not regulated | Not regulated | Not regulated | Not regulated |
| <b>14.5. Environmental hazards</b>      |               |               |               |               |
| Not regulated                           | Not regulated | Not regulated | Not regulated | Not regulated |
| No supplementary information available  |               |               |               |               |

### 14.6. Special precautions for user

#### Overland transport

Not regulated

#### Transport by sea

Not regulated

#### Air transport

Not regulated

#### Inland waterway transport

Not regulated

#### Rail transport

Not regulated

### 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

##### 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)

Not 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 1005/2009)

###### 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)

##### 2. National regulations

Listed on the EEC inventory EINECS (European Inventory of Existing Commercial Chemical Substances)

Listed on the TCSI (Taiwan Chemical Substance Inventory)

Listed on the Vietnam National Chemical Database (as amended through 31 July 2018)

###### Germany

Water hazard class (WGK) : Not classified according to Regulation Governing Systems for Handling Substances Hazardous to Waters (AwSV).

Hazardous Incident Ordinance (12. BImSchV) : Is not subject of the Hazardous Incident Ordinance (12. BImSchV)

###### Netherlands

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

#### 15.2. Chemical safety assessment

CSA has not been established

### SECTION 16: Other information

#### Indication of changes

| Section | Changed item  | Change | Comments |
|---------|---|--------|----------|
|         | SDS EU format according to COMMISSION REGULATION (EU) |        |          |

#### Abbreviations and acronyms:

# AMCIPATRICIN

## Safety Data Sheet

SDS EU format according to COMMISSION REGULATION (EU) 2020/878

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|     |                                  |
|-----|----------------------------------|
| SDS | SDS - Safety Data Sheet          |
| CAS | CAS - Chemical Abstracts Service |

### Abbreviations and acronyms:

|       |  |
|-------|--|
| GHS   | GHS - Globally Harmonised System   |
| CSR   | CSR - Chemical Safety Report   |
| 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                |
| DNEL  | Derived-No Effect Level  |
| EC50  | Effective concentration for 50 percent of test population (median effective concentration)         |
| IATA  | International Air Transport Association  |
| IMDG  | International Maritime Dangerous Goods   |
| LC50  | Lethal concentration for 50 percent of test population (median lethal concentration)               |
| LD50  | Lethal dose for 50 percent of test population (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   |
| RID   | Regulation concerning the International Carriage of Dangerous Goods by Railways                    |
| PVC   | PVC (Polyvinyl chloride).  |
| PNEC  | Predicted No-Effect Concentration  |
| PBT   | Persistent Bioaccumulative Toxic   |
| vPvB  | Very Persistent and Very Bioaccumulative   |
| ATE   | Acute Toxicity Estimate  |
| BCF   | Bioconcentration factor  |
| CLP   | Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008                        |
| REACH | Registration, Evaluation, Authorisation and Restriction of Chemicals, Regulation (EC) No 1907/2006 |

Sources of Key data  
Other information

- : Supplier information. Safety Data Sheet. REACH registration dossier.
- : 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. It is the user's responsibility to take mentioned precaution measures and ensure that this information is complete and sufficient for the use of this product.

### Full text of H- and EUH-statements:

|      |   |
|------|---|
| H372 | Causes damage to organs through prolonged or repeated exposure. |
| H302 | Harmful if swallowed  |

Safety Data Sheet (SDS), EU

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