

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

1.1. Product identifier

Product form	: Mono constituent substance
Trade name	: Amcipatricin Diascorbate
IUPAC name	: N – Dimethylaminoacetyl Partricin A, 2 – Dimethylamminoethylamide diascorbate
EC-No.	: Not available
CAS-No.	: 202748-83-2
REACH registration No.	: Not applicable
Formula	: C ₆₇ H ₁₀₃ N ₅ O ₁₉ • 2 C ₆ H ₈ O ₆
Synonyms	: SPA-S-843, SPK-843

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

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.

Ampicpatricin Diascorbate

Safety Data Sheet

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

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 Diascorbate	CAS-No.: 202748-83-2	≥ 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 (CO₂), dry chemical powder, foam. Water spray jet.

Ampicatricin Diascorbate

Safety Data Sheet

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.

Ampicpatricin Diascorbate

Safety Data Sheet

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No additional information available

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:

Provide adequate ventilation.

8.2.2. Personal protection equipment

Personal protective equipment:

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

Personal protective equipment symbol(s):



8.2.2.1. 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

8.2.2.2. 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

8.2.2.3. 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.

8.2.2.4. 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.

Ampicpatricin Diascorbate

Safety Data Sheet

Other information: According to COMMISSION REGULATION (EU) 2020/878

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	: 1634.8 g/mol
Odour	: Almost odorless.
Odour threshold	: Not available
Melting point	: 178.9 – 183.9°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	: 4.6~5.6 (1% solution)
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Viscosity, dynamic	: Not applicable
Solubility:	Soluble in water, 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

9.2.1. Information with regard to physical hazard classes

No additional information available

9.2.2. 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.

Amcipatricin Diascorbate

Safety Data Sheet

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

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 Diascorbate (202748-83-2)	
LD50 oral rat	> 2000 mg/kg
LD50 intravenous rat	12 mg/Kg
LD50 oral mouse	> 2000 mg/Kg
LD50 intravenous mouse	60 mg/kg
NOEL intravenous rat	0.2 mg/kg
Skin corrosion/irritation	: Not classified pH: 4.6~5.6 (1% solution)
Serious eye damage/irritation	: Not classified pH: 4.6~5.6 (1% solution)
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 Diascorbate (202748-83-2)

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 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

Amcipatricin Diascorbate

Safety Data Sheet

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

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 Diascorbate (202748-83-2)	
Persistence and degradability	Not determined

12.3. Bioaccumulative potential

Amcipatricin Diascorbate (202748-83-2)	
Partition coefficient n-octanol/water (Log Pow)	Not available
Bioaccumulative potential	Not available.

12.4. Mobility in soil

Amcipatricin Diascorbate (202748-83-2)	
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 Diascorbate (202748-83-2)	
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.

Ampicatricin Diascorbate

Safety Data Sheet

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

Ampicpatricin Diascorbate

Safety Data Sheet

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

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 B	IMD G	IAT A	AD N	RID
14.1. UN number or ID number				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.4. Packing group				
Not regulated	Not regulated	Not regulated	Not regulated	Not regulated
14.5. Environmental hazards				
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

Ampicpatricin Diascorbate

Safety Data Sheet

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

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)

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)

15.1.2. 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) 2020/878		

Abbreviations and acronyms:

Ampicatricin Diascorbate

Safety Data Sheet

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

CAS CAS - Chemical Abstracts Service

Ampicatricin Diascorbate

Safety Data Sheet

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

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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