

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 1/9

Publication: 03/05/2022

Revision: 03/05/2022

Version: 00



POLYMYXINI B SULFAS

SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

1.1 Product identifier

Product name:	Polymyxin B sulfate Polymyxini B sulfas Polymyxine B sulfaat Polymyxine B (sulfate de) Polymyxin B sulfat
N° CAS:	1405-20-5
N° EC:	215-774-7

1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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1.3 Details of the supplier of the safety data sheet

Company:	FAC SECUNDUM ARTEM NV Oostmalsebaan 1c (unit 5) 2960 Sint-Lenaarts Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

SECTION 2: HAZARDS IDENTIFICATION

2.1 Classification of the substance/mixture

Classification according to (EC) n° 1272/2008

Acute Tox. 4	H302
Acute Tox. 4	H332

2.2 Label elements

Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H302	Harmful if swallowed.
H332	Harmful if inhaled.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 2/9

Publication: 03/05/2022

Revision: 03/05/2022

Version: 00



POLYMYXINI B SULFAS

Precautionary statements:

P261

Avoid breathing dust/fumes/gas/mist/vapours/spray.

Additional applicable label elements:



2.3 Other hazards

None known.

PBT/vPvB: The substance is not considered PBT/vPvB according to criteria in Annex XIII.

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1 Substances

Product name:	Polymyxin B sulfate
IUPAC name:	<i>N</i> -[4-amino-1-[[1-[[4-amino-1-oxo-1-[[6,9,18-tris(2-aminoethyl)-15-benzyl-3-(1-hydroxyethyl)-12-(2-methylpropyl)-2,5,8,11,14,17,20-heptaoxo-1,4,7,10,13,16,19-heptacyclicotricos-21-yl]amino]butan-2-yl]amino]-3-hydroxy-1-oxobutan-2-yl]amino]-1-oxobutan-2-yl]-6-methyloctanamide; sulfuric acid
Synonyms:	Aerosporin Polymyxin B sulfate salt
N° CAS:	1405-20-5
N° EC:	215-774-7
Molecular Formula:	C ₄₃ H ₈₂ N ₁₆ O ₁₂ , H ₂ SO ₄ (Variable - sulfate salts of polypeptides)
Content:	Mixture of the sulfates of polypeptides produced by the growth of certain strains of <i>Paenibacillus polymyxa</i> , the main component being polymyxin B1. Potency: minimum 6500 IU/mg (dried substance).

3.2 Mixtures

Not applicable.

SECTION 4: FIRST AID MEASURES

4.1 Description of first aid measures

After inhalation:	Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.
After skin contact:	Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation or rash develops.
After eye contact:	Flush eyes for 15 minutes with plenty of water. Get medical attention immediately.
After ingestion:	Do not induce vomiting. Call a physician or poison control centre. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

4.2 Most important symptoms and effects, both acute and delayed

ACUTE TOXICITY: Eyes, Skin, Ingestion and Inhalation Exposure: None expected.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 3/9

Publication: 03/05/2022

Revision: 03/05/2022

Version: 00



POLYMYXINI B SULFAS

CHRONIC TOXICITY: Target Organ Statement: Kidney and nervous system, based on clinical use as described in the Physicians Desk Reference.

REPRODUCTIVE TOXICITY: Teratogenic Effects: Not teratogenic in rats or rabbits. FDA Pregnancy Category B.

SENSITIZATION: Allergic rashes have been rarely reported.

MEDICAL CONDITIONS AGGRAVATED: None known.

4.3 Indication of any immediate medical attention and special treatment needed

In case of discomfort or unconsciousness: Show this safety data sheet to a physician or emergency ward.

Antidote information: No specific antidote available.

SECTION 5: FIREFIGHTING MEASURES

5.1 Extinguishing media

Suitable extinguishing media: Water, carbon dioxide, dry chemical, foam, or other alternatives.

Unsuitable extinguishing media: Not available.

5.2 Special hazards arising from the substance/mixture

General hazards: May be combustible at high temperature.

Hazardous combustion products: Carbon monoxide, carbon dioxide, and nitrogen oxides.

5.3 Advice for firefighters

Surrounding fires: Use water spray to cool fire-exposed containers and structures.

Protection against fire: Not available.

Hazardous combustion products: Not available.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1 Personal precautions, protective equipment and emergency procedures

For non-emergency personnel

Wear personal protective equipment to avoid exposure – see section 8. Avoid generation of dust.

For emergency responders

Wear personal protective equipment to avoid exposure – see section 8. Avoid generation of dust.

6.2 Environmental precautions

Water spill: Do not empty into drains.

Land spill: Vacuum material with appropriate dust collection in place. Be aware of potential for dust explosion when using electrical equipment. If a vacuum is not available, lightly mist material and remove by sweeping or wet wiping. Wear appropriate equipment including eye protection, to avoid exposure.

Release notes: If the spill could potentially enter any waterway, including intermittent dry creeks, contact the local authorities. In the USA, contact the USA Coast Guard National Response Center toll free 800 424 8802.

6.3 Methods and material for containment and cleaning up

Use appropriate tools to put the spilled solid in a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and dispose of according to local and regional authority requirements. In case of large spill and leak, use a shovel to put the material into a convenient waste disposal container. Finish cleaning by spreading water on the contaminated surface and allow evacuating through the sanitary system.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 4/9

Publication: 03/05/2022

Revision: 03/05/2022

Version: 00



POLYMYXINI B SULFAS

6.4 Reference to other sections

See section 1 for emergency contact information, section 8 for personal protective equipment details, and section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE

7.1 Precautions for safe handling

Precautions for safe handling:	Not available.
Personal protection:	In the absence of adequate ventilation, suitable respiratory protection is required. The need for additional personal protective equipment including respirators, eye, and skin protection should be based on a job-specific risk assessment. Additional personal protective equipment may include chemical-resistant gloves and body covering, goggles, and face shield. Adequate eye protection is always required.
Technical protective measures:	Engineering controls are recommended to ensure adequate ventilation such that exposures do not exceed 1mg/m ³ for an eight-hour time weighted average exposure. With adequate ventilation, respiratory protection may not be needed.
Handling:	Work hygienic practices: Facilities storing or using this material should be equipped with an emergency eyewash and safety shower. Good personal hygiene practices should always be followed.

7.2 Conditions for safe storage, including any incompatibilities

Storage:	In an airtight container.
Conditions for safe storage, including any incompatibilities:	Keep dry and away from sources of ignition. Below 25 °C (77 °F) for up to five years in original unopened sales container. For Denmark: Store securely, inaccessible for unauthorised persons, separate from food, feedstuff etc.
Storage – away from:	Store protected from light.

7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1 Control parameters

OSHA'S hazardous components (29 CFR 1910.1020) EXPOSURE LIMITS AND GUIDELINES
OSHA PEL ACGIH TLV OTHER OEL (TWA)
Polymyxin B sulfate: 1.0 mg/m³

8.2 Exposure controls

Appropriate engineering control

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 5/9

Publication: 03/05/2022

Revision: 03/05/2022

Version: 00



POLYMYXINI B SULFAS

If dust is generated, provide local exhaust ventilation to control airborne levels below the OEL listed above.

Comments: This product is not specifically listed by OSHA as hazardous. This product may cause kidney and nervous system damage from overexposure to polymyxin B sulfate, based on clinical use as described in the Physicians Desk Reference. Under conditions of overexposure, this product may be hazardous.

Individual protection measures

Eye/face protection:	Safety glasses with side shields/goggles as appropriate when handling this material.
Skin protection:	Body covering.
Hand protection:	Chemical resistant gloves (nitrile or latex).
Respiratory protection:	Use an approved respirator suitable to provide level of protection required.
Thermal hazards:	Not determined.

Environmental exposure control

Not available.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, hygroscopic powder.
Odour:	Odourless.
Odour threshold:	Not relevant.
pH:	5.0 to 7.0 (20 g/L at 20 °C)
Melting/freezing point:	> 240 °C
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	0.6
Relative density:	Not available.
Solubility:	Practically insoluble in ethanol (96 per cent).
Solubility in water:	Freely soluble in water.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 6/9

Publication: 03/05/2022

Revision: 03/05/2022

Version: 00



POLYMYXINI B SULFAS

Oxidising properties: Not available.

9.2 Other information

Ignition temperature: 805 °C

Bulk density: approx. 250 kg/m³

Specific gravity: app. 1

SECTION 10: STABILITY AND REACTIVITY

10.1 Reactivity

Not available.

10.2 Chemical stability

Stable at normal temperatures and pressures.

10.3 Possibility of hazardous reactions

Not available.

10.4 Conditions to avoid

Fires, hot surfaces, and ignition sources.

10.5 Incompatible materials

Nitrogen oxides, carbon monoxide, carbon dioxide.

10.6 Hazardous decomposition products

Nitrogen oxides, carbon monoxide, irritating and toxic fumes and gases, carbon dioxide.

SECTION 11: TOXICOLOGICAL INFORMATION

11.1 Information on toxicological effects

Acute toxicity: Oral LD₅₀ (mouse): 790 mg/kg

Skin corrosion/irritation: Not determined.

Serious eye damage/irritation: Not determined.

Respiratory/skin sensitisation: Allergic skin rash possible.

Germ cell mutagenicity: Testing not conducted.

Carcinogenicity: Testing not conducted. Not listed by IARC. Not listed by NTP. Not listed by OSHA.

Reproductive toxicity: Testing not conducted.

Teratogenic effects: Not teratogenic in rats or rabbits. FDA Pregnancy Category B.

Summary of evaluation of the CMR properties: Not available.

STOT-single exposure: Not available.

STOT-repeated exposure: Not available.

Aspiration Hazard: Not available.

Other: Target organs: Kidney and nervous system based on clinical use as described in the Physicians Desk Reference.

11.2 Additional information on potential adverse human health effects and symptoms

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 7/9

Publication: 03/05/2022

Revision: 03/05/2022

Version: 00



POLYMYXINI B SULFAS

Eye contact:	Not available.
Skin contact:	Not available.
Inhalation:	Harmful if inhaled.
Ingestion:	Harmful if swallowed.
Aspiration:	Not available.

SECTION 12: ECOLOGICAL INFORMATION

12.1 Toxicity

Not available.

12.2 Persistence and degradability

Not available.

12.3 Bioaccumulative potential

Not available.

12.4 Mobility in soil

Not available.

12.5 Results of PBT and vPvB assessment

The substance is not considered PBT/vPvB according to criteria in Annex XIII.

12.6 Other adverse effects

The substance is possibly harmful for the aquatic environment, due to its antibiotic properties.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1 Waste treatment methods

Disposal (includes spills, empty containers): Dispose of any clean-up materials and waste residue according to applicable laws and regulations.

SECTION 14: TRANSPORT INFORMATION

Transport information according to ADR/RID/IMDG/ICAO/IATA

14.1 UN Number

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not regulated.

14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not relevant.

14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not relevant.

14.4 Packing group

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 8/9

Publication: 03/05/2022

Revision: 03/05/2022

Version: 00



POLYMYXINI B SULFAS

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : Not relevant.

14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),
IATA/ICAO (Air) : None.

14.6 Special precautions for user

None.

14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not relevant.

14.8 Additional transport information

Not available.

SECTION 15: REGULATORY INFORMATION

15.1 Safety, health and environmental regulations/legislation specific for the substance/mixture

Hazard symbol:



Irritant
Corrosive

Risk phrases:

R20/22 Harmful by inhalation and if swallowed.

Safety phrases:

S23 Do not breathe dust/fumes/gas/mist/vapours/spray.

15.2 Chemical safety assessment

No CSR.

SECTION 16: OTHER INFORMATION

16.1 Changes since the previous version

Not applicable.

16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail

Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

EN

FORM-06-14-01 (V00)

Page 9/9

Publication: 03/05/2022

Revision: 03/05/2022

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POLYMYXINI B SULFAS

STOT: Specific Target Organ Toxicity
UN (number): United Nations (number)
vPvB: very Persistent and very Bioaccumulative

16.3 Key literature references/sources for data

European Chemicals Agency.
<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

16.4 Method of classification in case of mixture

Not applicable.

16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

16.6 Training advisement

Not available

16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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16.8 Department issuing MSDS

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