Polymyxin B Sulfate

Material Safety Data Sheet

Revision Date: August, 2024

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

1.1. Product identifier

Product name: Polymyxin B Sulfate
CAS: 1405-20-5
EINECS: 215-774-7
INDEX: None.
REACH reg.: Deadlines according to REACH art. 23, has not expired.

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

Use: Anti-infective/antibiotic; ophthalmic, topical
Product code: A141, A142, A143, A147
Product name: Polymyxin B Sulfate
Chemical family: Sulfate salt of basic polypeptide derived from *B polymyxa*
Synonyms: Aerosporin

1.3. Details of the supplier of the safety data sheet

Name: BIOTIKA a.s.
Address: Slovenska Lupca 566,
PIN 976 13
Slovak Republic
Tel.: 00421/48/4368 111
Fax: 00421/48/418 7060
E-mail: biotika@biotika.eu.com

1.4. Emergency telephone number

Biotika a.s.: 00421 48 4368 111

2. SECTION: Hazards identification.

2.1. Classification of the substance or mixture

	GHS07	Acute Tox. 4 H332 Harmful if inhaled Acute Tox. 4 H302 Harmful if swallowed.

2.2. Label elements:

GHS label elements

The substance is classified and labeled according to the Globally Harmonized System (GHS).

Hazard pictograms

	GHS07	

Signal word

Warning

Hazard statements

H332+H302 Harmful if inhaled or swallowed.

Precautionary statements

P261	Avoid breathing dust/fume/gas/mist/vapors/spray
P264	Wash thoroughly after handling.
P270	Do not eat, drink, or smoke when using this product.
P271	Use only outdoors or in a well-ventilated area.
P301+P312	If swallowed: Call a poison center/doctor if you feel unwell.
P330	Rinse mouth.
P304+P340	IF INHALED: Remove person to fresh air and keep comfortable for breathing.
P501	Dispose of contents/container in accordance with local/ regional/ national/ international regulations.

Classification system:

NFPA rating (scale 0 - 4)

	Health = 3 Fire = 0 Reactivity = 0
	Health = 2
	Fire = 0 Reactivity = 0

HMIS-ratings (scale 0 - 4)

2.3. Other hazards:

Results of PBT and vPvB assessment:

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

3. SECTION: Composition/Information on ingredients.

3.1. Substances:

Chemical characterization (substance):

CAS:	1405-20-5
Chemical characteristics:	cyclic polypeptide
EC:	215-774-7

3.2. Mixtures:

N/A

4. SECTION: First aid measures.

4.1. Description of first aid measures:

General information:

Symptoms of poisoning may even occur after several hours; therefore, medical observation for at least 48 hours after the accident.

After eye contact:

Flush eyes for 15 minutes with plenty of water. Get medical attention 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 swallowing:

Do not induce vomiting. Call a physician or poison control center. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

After inhalation:

Supply fresh air. If required, provide artificial respiration. Keep patient warm. Consult doctor if symptoms persist.

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

May cause anemia, cough, CNS depression, drowsiness, headache, heart damage, lassitude (weakness, exhaustion), liver damage, narcosis, reproductive effects, teratogenic effects. No further relevant information available.

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.

5. SECTION: Firefighting media.

5.1. Extinguishing media:

Water, carbon dioxide, dry chemical, foam, or other alternatives.

5.2. Special hazards arising from the substance or mixture:

General hazards:

May be combustible at high temperature.

Hazardous combustion products:

Carbon monoxide, carbon dioxide, and nitrogen oxides.

Flash point and method:

No applicable information identified.

Flammable limits:

No applicable information identified.

Autoignition temperature:

No applicable information identified.

Flammable class:

No applicable information identified.

Sensitivity to static charge:

No applicable information identified.

5.3. Advice for firefighters:

Use water spray to cool fire-exposed containers and structures.
Protective equipment: Mouth respiratory protective device.

6. SECTION: Accidental release measures.

6.1. Personal precautions, protective equipment and emergency response:

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

6.2. Environmental precautions:

Do not allow to enter sewers / surface or ground water.

6.3. Methods and materials for containment and cleaning up:

Use appropriate tools to put the spilled solid 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 cage 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.

6.4. References to other sections:

PAC-1: Substance is not listed.
PAC-2: Substance is not listed.
PAC-3: Substance is not listed.

7. SECTION: Handling and storage.

7.1. Precautions for safe handling:

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.
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.

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:

Keep dry and away from sources of ignition. Below 25ºC (77ºF) for up to five years in original unopened sales container.
For Denmark: Store securely, inaccessible for unauthorized persons, separate from food, feedstuff etc.

7.3. Specific end uses:

No further relevant information available.

8. SECTION: Exposure control / personal protection.

8.1. Control parameters:

Exposure limits and guidelines

OSHA'S hazardous components (29 CFR 1910.1020)
OSHA PEL ACGIH TLV OTHER OEL (TWA)

Polymyxin B Sulfate

ppm	mg/m^3	ppm	mg/m^3	ppm	mg/m^3
NL	NL	NL	NL	NL	1.0

Other country exposure limits:

Not listed.

8.2. Exposure controls:

Appropriate engineering controls:

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

Personal protective equipment:

General protective and hygienic measures:

Wash hands before breaks and at the end of work.

Breathing equipment:

In case of brief exposure or low pollution use respiratory filter device. In case of intensive or longer exposure use respiratory protective device that is independent of circulating air.

Protection of hands:

The glove material has to be impermeable and resistant to the product/ the substance/ the preparation. Due to missing tests no recommendation to the glove material can be given for the product/ the preparation/ the chemical mixture. Selection of the glove material on consideration of the penetration times, rates of diffusion and the degradation

Material of gloves:

The selection of the suitable gloves does not only depend on the material, but also on further marks of quality and varies from manufacturer to manufacturer.

Penetration time of glove material:

The exact break through time has to be found out by the manufacturer of the protective gloves and has to be observed.

Eye and face protection:

Wear safety glasses with side shields or goggles as appropriate when handling this material.

9. SECTION: Physical and chemical properties.

9.1. Information on basic physical and chemical properties:

Physical state:	Solid.
Appearance:	Crystalline powder.
Color:	White to buff.
Odor:	Odorless.
Odor threshold:	Not relevant.
pH:	No applicable information found.
Vapor pressure:	No applicable information found.
Vapor density:	0.6
Evaporation rate:	No applicable information found.
Freezing point:	Not applicable.
Melting point:	234 °C
Boiling point:	No applicable information found.
Flash point:	No applicable information found.
Ignition temperature:	805°C
Bulk density:	approx. 250 kg/m^3
Decomposition temperature:	No applicable information found.
Flammability:	No applicable information found.

Upper/lower flammability or explosive limits (vol-%): No applicable information found.

Auto-ignition temperature:	No applicable information found.
Soluble in water:	Soluble.
Solubility:	PBS (pH 7.2): 2 mg/ml
Density:	No applicable information found.
Specific gravity:	app. 1.
Viscosity:	No applicable information found.
Explosive properties:	No applicable information found.
Oxidizing properties:	No applicable information found.
Molecular formula:	Variable – sulfate salts of polypeptides
Molecular weight:	No applicable information found.
Coefficient of oil and water:	No applicable information found.

9.2. Other information:

No further relevant information available.

10. SECTION: Stability and reactivity.

10.1. Reactivity:
No further relevant information available.

10.2. Chemical stability:
Stable at normal temperatures and pressures.

10.3. Possibility of hazardous reactions:
No dangerous reactions known.

10.4. Conditions to avoid:
Fires, hot surfaces, and ignition sources.

10.5. Incompatible materials:
Strong oxidizing agents.

10.6. Hazardous decomposition products:
Nitrogen oxides, carbon monoxide, irritating and toxic fumes and gases, carbon dioxide.

11. SECTION: Toxicological information.

RTECS Number:	TR1150000
Acute dermal LD50:	Not determined.
Acute oral LD50:	790 mg/kg (mouse).
Acute intraperitoneal LD 50:	20,5 mg/kg (mouse).
Acute subcutaneous LD50:	59,5 mg/kg (mouse)
Acute inhalation LC50:	Not determined.
Eye effects:	Not determined.
Skin effects:	No irritating effect.
Sensitization:	Allergic skin rash possible.
Target organs:	Kidney and nervous system based on clinical use as described in the Physicians' Desk Reference.
Carcinogenicity:	Testing not conducted.
Listed by IARC:	No
Listed by NTP:	No
Listed by OSHA:	No
Mutagenicity:	Testing not conducted.
Reproductive effects:	Testing not conducted.
Teratogenic effects:	Not teratogenic in rats or rabbits. FDA Pregnancy Category B.

12. SECTION: Ecological information.

12.1. Toxicity:

Aquatic toxicity:
No further relevant information available.

12.2. Persistence and degradability:

No applicable information found.

12.3. Bioaccumulative potential:

No applicable information found.

12.4. Mobility in soil:

No applicable information found.

12.5. Additional ecological information:

Water hazard class 1 (Self-assessment): slightly hazardous for water. Do not allow undiluted product or large quantities of it to reach ground water, water course or sewage system.

12.6. Results of PBT and vPvB assessment:

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

12.7. Other adverse effects:

No applicable information found.

13. SECTION: Disposal consideration.

13.1. Waste treatment methods:

Recommendation:
Must not be disposed of together with household garbage. Do not allow product to reach sewage system.
Uncleaned packagings:
Recommendation: Disposal must be made according to official regulations.

14. SECTION: Transport information.

14.1. UN number:

Not regulated.

14.2. UN proper shipping name:

Not regulated.

14.3. Transport hazard class(es):

Not regulated.

14.4. Packing group:

Not regulated.

14.5. Environmental hazards:

Not applicable.

14.6. Special precautions for user:

Not applicable.

14.7. Transport in bulk according to Annex II MARPOL 73/78 and the IBC Code:

Not applicable.

USA DOT (DEPARTMENT OF TRANSPORTATION)
Proper Shipping Name: Not regulated

CANADA TRANSPORT OF DANGEROUS GOODS
Proper Shipping Name: Not regulated.

AIR (ICAO/IATA)
Proper Shipping Name: Not regulated.

VESSEL (IMO/IMDG)
Proper Shipping Name: Not regulated.

EUROPEAN TRANSPORTATION:
ADR/RID HAZARD CLASSIFICATION: Not regulated.

U.S. CUSTOMS HARMONIZATION NUMBER: Not regulated.

15. SECTION: Regulatory information.

15.1. Safety, health and environmental regulation/legislation specific for the substance or mixture:

No further relevant information available.

Sara
Section 355 (extremely hazardous substances):
Substance is not listed.
Section 313 (Specific toxic chemical listings):
Substance is not listed.
TSCA (Toxic Substances Control Act):
Substance is not listed.
Hazardous Air Pollutants:
Substance is not listed.

Proposition 65
Chemicals known to cause cancer:
Substance is not listed.
Chemicals known to cause reproductive toxicity for females:
Substance is not listed.
Chemicals known to cause reproductive toxicity for males:
Substance is not listed.
Chemicals known to cause developmental toxicity:
Substance is not listed.

Carcinogenic categories
EPA (Environmental Protection Agency)
Substance is not listed.
TLV (Threshold Limit Value)
Substance is not listed.
NIOSH-Ca (National Institute for Occupational Safety and Health)
Substance is not listed.
Chemical safety assessment:
A Chemical Safety Assessment has not been carried out.

15.2. Chemical safety assessment:

A Chemical Safety Assessment has not been carried out.

16. SECTION: Other information.

Reason for issue: EC regulation, REACH and CLP
Contact Information: See Section 1
Revision summary: This document has undergone significant changes and should be reviewed in its entirety.

	HMIS RATING	NFPA RATING
Health	ND	ND
Flammability	ND	ND
Physical hazard	ND	ND
Personal protection	ND	ND
Incompatibilities	ND	ND

Data sources:

Micromedex DrugDex; Mosby's Drug Consult; Physicians Desk Reference; RTECS, PubChem, Kucers'The use of antibiotics, ECHA.

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Glossary:

ACGIH – American Conference of Governmental Hygienists
AIHA – American Industrial Hygiene Association
BEI – Biological Exposure Index
CAS – Chemical Abstract Service Registry Number
CSR – Chemical Safety Report
CERCLA – Comprehensive Environmental Response Compensation and Liability Act of 1989
CHEMTREC – Chemical Transportation Emergency Center
DOT – Department of Transportation (USA)
EC – European Community
EINECS – European Inventory of Existing Chemical Substances
ELINCS - European List of New Chemical Substances
EPA – Environmental Protection Agency
FDA – United States Food and Drug Administration
HEPA- High Efficiency Particulate Air (Filter)
HMIS – Hazardous Material Information System
IARC- International Agency on Research for Cancer
ICAO/IATA – International Civil Aviation Organization/International Air Transport Association
IMO – International Maritime Organization
LEL – Lower Explosive Limit
MSDS – Material Safety Data Sheet
MSHA – Mine Safety and Health Administration
NA – Not Applicable
NADA – New Animal Drug Application

NAIF – No Applicable Information Found
NCI – National Cancer Institute
ND – Not Determined
NFPA – National Fire Protection Association
NIOSH – National Institute for Occupational Health and Safety
NL – Not Listed
NOS – Not Otherwise Specified
NTP – National Toxicology Program
OEL – Occupational Exposure Limit
OSHA – Occupational Safety and Health Administration
PEL – Permissible Exposure Limit (USA)
RCRA – Resource Conservation and Recovery Act
RQ – Reportable Quantity
RTECS – Registry of Toxic Effects of Chemical Substances
SARA – Superfund Amendments and Reauthorization Act
STEL – Short Term Exposure Limit
TLV – Threshold Limit Value
TPQ – Threshold Planning Quantity
TSCA – Toxic Substances Control Act
TWA – Time Weighted Average
UEL – Upper Explosive Limit
UN – United Nations
WEEL – Workplace Environmental Exposure Level (USA - AIHA)