

Safety Data Sheet

according to the REACH Regulation (EC) 1907/2006 amended by Regulation (EU) 2020/878

Reference number: P0145

Issue date: 29/05/2024 Revision date: 29/05/2024 Supersedes version of: 16/03/2018 Version: 3.0

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

1.1. Product identifier

Product form : Substance
Trade name : Polymixin B sulfate
EC-No. : 215-774-7
CAS-No. : 1405-20-5
Product code : P0145
Formula : $C_{55}H_{96}N_{16}O_{13} \cdot 2H_2SO_4$
Product group : Raw material

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.
Function or use category : Raw material

1.2.2. Uses advised against

No additional information available

1.3. Details of the supplier of the safety data sheet

Distributor

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

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30008100 (outside office hours)

Country	Organisation/Company	Address	Emergency number	Comment
	World Health Organization world directory of poison centres	http://apps.who.int/poisoncentres/		Consult website for a local poison centre
Ireland	National Poisons Information Centre Beaumont Hospital	PO Box 1297 Beaumont Road 9 Dublin	+353 1 809 2566 (Healthcare professionals-24/7) +353 1 809 2166 (public, 8am - 10pm, 7/7)	

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

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

Acute toxicity (oral), Category 4

H302

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Full text of H- and EUH-statements: see section 16

Adverse physicochemical, human health and environmental effects

Harmful if swallowed.

2.2. Label elements

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

Hazard pictograms (CLP)

:



GHS07

Signal word (CLP)

: Warning

Hazard statements (CLP)

: H302 - Harmful if swallowed.

Precautionary statements (CLP)

: P264 - Wash hands thoroughly after handling.

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Comments

: Content: > 6500 IU/mg

Substance type

: Multi-constituent

Name	Product identifier	%
Polymixin B sulfate	CAS-No.: 1405-20-5 EC-No.: 215-774-7	100

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general

: Call a poison center or a doctor if you feel unwell.

First-aid measures after inhalation

: Remove person to fresh air and keep comfortable for breathing.

First-aid measures after skin contact

: Wash skin with plenty of water.

First-aid measures after eye contact

: Rinse eyes with water as a precaution.

First-aid measures after ingestion

: Rinse mouth. Call a poison center or a doctor if you feel unwell.

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

Symptoms/effects

: Nervous system disorder. Damage to kidneys. Ingestion may cause nausea, vomiting and diarrhea.

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

: Water spray. Dry powder. Foam.

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5.2. Special hazards arising from the substance or mixture

Explosion hazard : Product is not explosive.
Hazardous decomposition products in case of fire : - COx. - NOx. - SOx.

5.3. Advice for firefighters

Firefighting instructions : Prevent fire fighting water from entering the environment.
Protection during firefighting : Do not enter fire area without proper protective equipment, including respiratory protection. Do not attempt to take action without suitable protective equipment. Self-contained breathing apparatus. Complete protective clothing.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Emergency procedures : Ventilate spillage area. Ensure adequate air ventilation. Avoid raising dust.

6.1.2. For emergency responders

Protective equipment : Do not attempt to take action without suitable protective equipment. Wear proper protective equipment. [In case of inadequate ventilation] wear respiratory protection. For further information refer to section 8: "Exposure controls/personal protection".

6.2. Environmental precautions

Avoid release to the environment. Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

Methods for cleaning up : Mechanically recover the product. Sweep up dry powder and dispose properly. To clean the floor or objects contaminated by this product, use : Water.
Other information : Dispose of materials or solid residues at an authorized site.

6.4. Reference to other sections

For further information refer to section 8.

SECTION 7: Handling and storage

7.1. Precautions for safe handling

Precautions for safe handling : Ensure good ventilation of the work station. Wear personal protective equipment. Handle in accordance with good industrial hygiene and safety procedures.
Hygiene measures : Do not eat, drink or smoke when using this product. Always wash hands after handling the product.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, cool, well-ventilated area. Keep container tightly closed. Protect from moisture. Protect from sunlight.
Maximum storage period : 5 year
Storage temperature : 2 – 8 °C

7.3. Specific end use(s)

For professional use only. Duchefa Biochemie B.V. products are intended only for "in vitro laboratory" research purposes.

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SECTION 8: Exposure controls/personal protection

8.1. Control parameters

8.1.1 National occupational exposure and biological limit values

Polymixin B sulfate (1405-20-5)

EU - Indicative Occupational Exposure Limit (IOEL)

IOEL TWA	0,0005 mg/m ³
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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:

Ensure good ventilation of the work station.

8.2.2. Personal protection equipment

Personal protective equipment symbol(s):



8.2.2.1. Eye and face protection

Eye protection			
Type	Field of application	Characteristics	Standard
Safety glasses	Dust		EN 166

8.2.2.2. Skin protection

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Hand protection					
Type	Material	Permeation	Thickness (mm)	Penetration	Standard
Gloves	Nitrile rubber (NBR)	6 (> 480 minutes)	0,11		EN ISO 374

8.2.2.3. Respiratory protection

Respiratory protection			
Device	Filter type	Condition	Standard
Dust mask	Type P2	Dust protection	EN 143

8.2.2.4. Thermal hazards

No additional information available

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8.2.3. Environmental exposure controls

Environmental exposure controls:

Avoid release to the environment.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Colour	: White.
Appearance	: Powder. Crystalline powder.
Molecular mass	: 1385 g/mol
Odour	: Odourless.
Odour threshold	: Not available
Melting point	: Not available
Freezing point	: Not applicable
Boiling point	: Not available
Flammability	: Non flammable.
Explosive limits	: Not applicable
Lower explosion limit	: Not applicable
Upper explosion limit	: Not applicable
Flash point	: Not applicable
Auto-ignition temperature	: Not applicable
Decomposition temperature	: Not available
pH	: 5 – 7
pH solution	: Not available
Viscosity, kinematic	: Not applicable
Solubility	: Soluble in water.
Partition coefficient n-octanol/water (Log Kow)	: Not available
Vapour pressure	: Not available
Vapour pressure at 50°C	: Not available
Density	: Not available
Relative density	: Not available
Relative vapour density at 20°C	: 0,6
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 storage, handling and use.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None under normal conditions.

10.4. Conditions to avoid

Heat. High temperature. Light (daylight). Moisture.

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10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Thermal decomposition generates : - NOx. - COx. - SOx.

SECTION 11: Toxicological information

11.1. Information on hazard classes as defined in Regulation (EC) No 1272/2008

Acute toxicity (oral) : Harmful if swallowed.
Acute toxicity (dermal) : Not classified
Acute toxicity (inhalation) : Not classified

Polymixin B sulfate (1405-20-5)	
LD50 oral rat	790 mg/kg
Skin corrosion/irritation	: Not classified pH: 5 – 7
Serious eye damage/irritation	: Not classified pH: 5 – 7
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

Polymixin B sulfate (1405-20-5)	
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/mixture does not contain substance(s) 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 at a concentration equal to or greater than 0,1 %

11.2.2. Other information

Other information : See actual entry in RTECS for complete information: TR1150000

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : The product is not considered harmful to aquatic organisms nor to cause long-term adverse effects in the environment.
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

No additional information available

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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. Endocrine disrupting properties

Adverse effects on the environment caused by endocrine disrupting properties : The substance/mixture does not contain substance(s) 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 at a concentration equal to or greater than 0,1 %.

12.7. 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 of contents/container in accordance with licensed collector's sorting instructions.
 Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

In accordance with ADR / IMDG / IATA

ADR	IMDG	IATA
14.1. UN number or ID number		
Not regulated	Not regulated	Not regulated
14.2. UN proper shipping name		
Not regulated	Not regulated	Not regulated
14.3. Transport hazard class(es)		
Not regulated	Not regulated	Not regulated
14.4. Packing group		
Not regulated	Not regulated	Not regulated
14.5. Environmental hazards		
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

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Air 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

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

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 to the Hazardous Incident Ordinance (12. BImSchV)

Netherlands

SZW-lijst van kankerverwekkende stoffen : The substance is not listed

SZW-lijst van mutagene stoffen : The substance is not listed

SZW-lijst van reprotoxische stoffen –

Borstvoeding

SZW-lijst van reprotoxische stoffen –

Vruchtbaarheid

SZW-lijst van reprotoxische stoffen –

Ontwikkeling

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

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SECTION 16: Other information

Indication of changes			
Section	Changed item	Change	Comments
	Adverse health effects caused by endocrine disrupting properties	Added	
	Revision date	Modified	
	Supersedes	Added	
	Flammability	Added	
	Regulatory framework	Added	
	Substance type	Added	
1.1	Formula	Modified	
2.1	Adverse physicochemical, human health and environmental effects	Added	
2.1	Classification according to Regulation (EC) No. 1272/2008 [CLP]	Modified	
2.2	Precautionary statements (CLP)	Modified	
2.2	Hazard statements (CLP)	Modified	
4.1	First-aid measures after skin contact	Added	
4.1	First-aid measures after inhalation	Added	
4.1	First-aid measures after eye contact	Added	
4.1	First-aid measures general	Added	
4.1	First-aid measures after ingestion	Added	
4.3	Other medical advice or treatment	Added	
5.1	Suitable extinguishing media	Added	
5.2	Hazardous decomposition products in case of fire	Added	
5.3	Protection during firefighting	Modified	
6.1	Protective equipment	Modified	
6.1	Emergency procedures	Modified	
6.2	Environmental precautions	Modified	
6.3	Other information	Added	
6.3	Methods for cleaning up	Modified	
6.4	Reference to other sections (8, 13)	Added	
7.1	Hygiene measures	Added	
7.1	Precautions for safe handling	Modified	
8.2	Environmental exposure controls	Added	
8.2	Hand protection	Added	
8.2	Appropriate engineering controls	Added	
8.2	Eye protection	Modified	

Polymixin B sulfate

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Indication of changes			
Section	Changed item	Change	Comments
9.1	Viscosity, kinematic	Added	
9.1	Freezing point	Added	
9.1	Flash point	Added	
9.1	Explosive limits (vol %)	Added	
9.1	Auto-ignition temperature	Added	
10.6	Hazardous decomposition products	Modified	
11.1	ATE CLP (oral)	Modified	
12.1	Ecology - general	Added	
12.6	Adverse effects on the environment caused by endocrine disrupting properties	Added	
13.1	Waste treatment methods	Modified	
16	Data sources	Modified	
16	Abbreviations and acronyms	Modified	

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
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
BLV	Biological limit value
BOD	Biochemical oxygen demand (BOD)
COD	Chemical oxygen demand (COD)
DMEL	Derived Minimal Effect level
DNEL	Derived-No Effect Level

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Abbreviations and acronyms:	
EC-No.	European Community number
EC50	Median effective concentration
EN	European Standard
IARC	International Agency for Research on Cancer
NOAEL	No-Observed Adverse Effect Level
NOEC	No-Observed Effect Concentration
OECD	Organisation for Economic Co-operation and Development
OEL	Occupational Exposure Limit
PNEC	Predicted No-Effect Concentration
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
STP	Sewage treatment plant
ThOD	Theoretical oxygen demand (ThOD)
TLM	Median Tolerance Limit
VOC	Volatile Organic Compounds
CAS-No.	Chemical Abstract Service number
N.O.S.	Not Otherwise Specified
vPvB	Very Persistent and Very Bioaccumulative
ED	Endocrine disrupting properties

Data sources : 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. ECHA (European Chemicals Agency).

Full text of H- and EUH-statements:	
Acute Tox. 4 (Oral)	Acute toxicity (oral), Category 4
H302	Harmful if swallowed.

Safety Data Sheet (SDS), EU Duchefa 2023

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.