

Colistin sulfate

Safety Data Sheet

900918 / 571644

according to Regulation (EC) No. 1907/2006 (REACH) with its amendment Regulation (EU) 2015/830

Version: 2.0

Issue date: 22/11/2019 Revision date 22/09/2020
Supersedes 22/11/2019

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

1.1. Product identifier

Product form : Substance
Substance name : Colistin sulfate
EC-No. : 215-034-3
CAS-No. : 1264-72-8
Product code : 900918 / 571644
Synonyms : Polymixin E sulfate
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 : Pharmaceutical industry
Use of the substance/mixture : Active ingredient for the preparation of pharmaceuticals
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

Supplier

Duchefa Farma BV
A. Hofmanweg 71
2031BH Haarlem - Nederland
T +31(0)23-5319093
farma@duchefa.nl - www.duchefa-farma.com

1.4. Emergency telephone number

Emergency number : Supplier contact information:
+31(0)23-5319093 (M-F 09:00-17:00)
+31(0)6-30109355 (outside office hours)

Organisation/Company	Address	Comment
Guy's & St Thomas' Poisons Unit Medical Toxicology Unit, Guy's & St Thomas' Hospital Trust	Avonley Road SE14 5ER London	

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 3

H301

Full text of H statements : see section 16

Adverse physicochemical, human health and environmental effects

No additional information available

2.2. Label elements

Labelling according to Regulation (EC) No. 1272/2008 [CLP] Extra labelling to display Extra classification(s) to display

Hazard pictograms (CLP)



GHS06

Signal word (CLP)

: Danger

Hazard statements (CLP)

: H301 - Toxic if swallowed.

Precautionary statements (CLP)

: P261 - Avoid breathing dust.
P280 - Wear eye protection, face protection, protective clothing, protective gloves.
P301+P310 - IF SWALLOWED: Immediately call a POISON CENTER/doctor

2.3. Other hazards

No additional information available

SECTION 3: Composition/information on ingredients

3.1. Substances

Substance type

: Antibiotics

Name	Product identifier	%	Classification according to Regulation (EC) No. 1272/2008 [CLP]
Colistin sulfate	(CAS-No.) 1264-72-8 (EC-No.) 215-034-3	100	Acute Tox. 3 (Oral), H301

Full text of H-statements: see section 16

3.2. Mixtures

Not applicable

SECTION 4: First aid measures

4.1. Description of first aid measures

First-aid measures general

: If medical advice is needed, have product container or label at hand.

First-aid measures after inhalation

: Remove person to fresh air and keep comfortable for breathing. If you feel unwell, seek medical advice.

First-aid measures after skin contact

: Remove affected clothing and wash all exposed skin area with mild soap and water, followed by warm water rinse.

First-aid measures after eye contact : Rinse immediately with plenty of water
Obtain medical attention if pain, blinking or redness persists.

First-aid measures after ingestion : Rinse mouth.
Induce vomiting if person is conscious
Seek medical attention immediately.

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

No additional information available

SECTION 5: Firefighting measures

5.1. Extinguishing media

Suitable extinguishing media : All extinguishing agents can be used.

5.2. Special hazards arising from the substance or mixture

Fire hazard : No fire hazard.
Explosion hazard : Product is not explosive.
Hazardous decomposition products in case of fire : Sulphur oxides
Nitrogen oxides
Carbon oxides (CO, CO₂).

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. Wear proper protective equipment.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

6.1.1. For non-emergency personnel

Protective equipment : Dustmask with filtertype P3. Eye protection. Use rubber or synthetic gloves (EN 374).
Emergency procedures : Only qualified personnel equipped with suitable protective equipment may intervene.

6.1.2. For emergency responders

Protective equipment : Use self-contained breathing apparatus and chemically protective clothing.

6.2. Environmental precautions

Prevent product from entering drains.

6.3. Methods and material for containment and cleaning up

For containment : Stop leak if safe to do so.
Methods for cleaning up : Sweep up dry powder and dispose properly. Hose down area with water.

6.4. Reference to other sections

No additional information available

SECTION 7: Handling and storage**7.1. Precautions for safe handling**

Precautions for safe handling : Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for safe storage, including any incompatibilities

Storage conditions : Store in dry, well-ventilated area
Keep container tightly closed.
Protect from moisture.
Protect from sunlight.

Storage temperature : 15 - 25 °C

Storage area : 6.1.

7.3. Specific end use(s)

No additional information available

SECTION 8: Exposure controls/personal protection**8.1. Control parameters**

No additional information available

8.2. Exposure controls**Appropriate engineering controls:**

Technical measures and appropriate working operations should have priority over the use of personal protective equipment.

Personal protective equipment:

Safety glasses. Dust/aerosol mask with filter type P3. Gloves.

Hand protection:

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

Eye protection:

Safety glasses (to European standard EN 166 or equivalent)

Skin and body protection:

Protective clothing (with elasticated cuffs and closed neck)

Respiratory protection:

Dustmask with filter type P3



SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state	: Solid
Appearance	: Powder.
Colour	: White to off-white.
Odour	: No data available
Odour threshold	: No data available
pH	: 4 - 6 (1% solution)
Relative evaporation rate (butylacetate=1)	: No data available
Melting point	: No data available
Freezing point	: No data available
Boiling point	: No data available
Flash point	: No data available
Auto-ignition temperature	: No data available
Decomposition temperature	: No data available
Flammability (solid, gas)	: No data available
Vapour pressure	: No data available
Relative vapour density at 20 °C	: No data available
Relative density	: No data available
Solubility	: Soluble in water.
Log Pow	: No data available
Viscosity, kinematic	: No data available
Viscosity, dynamic	: No data available
Explosive properties	: No data available
Oxidising properties	: No data available
Explosive limits	: No data available

9.2. Other information

No additional information available

SECTION 10: Stability and reactivity

10.1. Reactivity

Stable under normal conditions.

10.2. Chemical stability

Stable under normal conditions.

10.3. Possibility of hazardous reactions

None known.

10.4. Conditions to avoid

Direct sunlight

Water, humidity.

10.5. Incompatible materials

Strong oxidizers.

10.6. Hazardous decomposition products

Carbon dioxide
Carbon monoxide
Nitrogen oxides
Sulphur oxides.

SECTION 11: Toxicological information

11.1. Information on toxicological effects

Acute toxicity : Toxic if swallowed.

Colistin sulfate (1264-72-8)	
LD50 oral rat	121 mg/kg

Skin corrosion/irritation : Not classified
pH: 4 - 6 (1% solution)

Serious eye damage/irritation : Not classified
pH: 4 - 6 (1% solution)

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

SECTION 12: Ecological information

12.1. Toxicity

Ecology - general : There are no available data for a classification.

12.2. Persistence and degradability

Colistin sulfate (1264-72-8)	
Persistence and degradability	Biodegradable.

12.3. Bioaccumulative potential

Colistin sulfate (1264-72-8)	
Bioaccumulative potential	Low bioaccumulation potential.

12.4. Mobility in soil

No additional information available

12.5. Results of PBT and vPvB assessment

No additional information available

12.6. Other adverse effects

Other adverse effects : None known.

SECTION 13: Disposal considerations

13.1. Waste treatment methods

Regional legislation (waste) : Disposal must be done according to official regulations.
 Waste treatment methods : Avoid release to the environment.
 Product/Packaging disposal recommendations : Dispose in a safe manner in accordance with local/national regulations.

SECTION 14: Transport information

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

ADR	IATA
14.1. UN number	
2811	2811
14.2. UN proper shipping name	
TOXIC SOLID, ORGANIC, N.O.S.	Toxic solid, organic, n.o.s.
14.3. Transport hazard class(es)	
6.1	6.1
	
14.4. Packing group	
III	III
14.5. Environmental hazards	
Dangerous for the environment : No	Dangerous for the environment : No
No supplementary information available	

14.6. Special precautions for user

. Overland transport

Classification code (ADR) : T2
 Special provisions (ADR) : 274, 614
 Limited quantities (ADR) : 5kg
 Excepted quantities (ADR) : E1
 Packing instructions (ADR) : P002, IBC08, LP02, R001
 Special packing provisions (ADR) : B3
 Mixed packing provisions (ADR) : MP10
 Portable tank and bulk container instructions (ADR) : T1
 Portable tank and bulk container special provisions (ADR) : TP33
 Tank code (ADR) : SGAH, L4BH
 Tank special provisions (ADR) : TU15, TE19
 Vehicle for tank carriage : AT
 Transport category (ADR) : 2

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Special provisions for carriage - Bulk (ADR) : VC1, VC2, AP7

Special provisions for carriage - Loading, unloading and handling (ADR) : CV13, CV28

Special provisions for carriage - Operation (ADR) : S9

Hazard identification number (Kemler No.) : 60

Orange plates :

60
2811

Tunnel restriction code (ADR) : E

EAC code : 2X

- Air transport

PCA Excepted quantities (IATA) : E1

PCA Limited quantities (IATA) : Y645

PCA limited quantity max net quantity (IATA) : 10kg

PCA packing instructions (IATA) : 670

PCA max net quantity (IATA) : 100kg

CAO packing instructions (IATA) : 677

CAO max net quantity (IATA) : 200kg

Special provisions (IATA) : A3, A5

ERG code (IATA) : 6L

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

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**

No REACH Annex XVII restrictions

Colistin sulfate is not on the REACH Candidate List

Colistin sulfate is not on the REACH Annex XIV List

15.1.2. National regulations

No additional information available

15.2. Chemical safety assessment

No chemical safety assessment has been carried out

SECTION 16: Other information

Indication of changes:

1.1	Product code	Added	article number added
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Abbreviations and acronyms:

SDS	Safety Data Sheet
RID	Regulations concerning the International Carriage of Dangerous Goods by Rail
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation (EC) No 1907/2006
IMDG	International Maritime Dangerous Goods
IATA	International Air Transport Association
ADR	European Agreement concerning the International Carriage of Dangerous Goods by Road
ADN	European Agreement concerning the International Carriage of Dangerous Goods by Inland Waterways
CLP	Classification Labelling Packaging Regulation; Regulation (EC) No 1272/2008

Data sources : Supplier. EP.

Full text of H- and EUH-statements:

Acute Tox. 3 (Oral)	Acute toxicity (oral), Category 3
H301	Toxic if swallowed.

SDS EU (REACH Annex II) duchefa nieuwe logo

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.