

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 filtertype 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 : Dispose in a safe manner in accordance with local/national recommendations 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

Safety Data Sheet

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

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 : 

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 |
|-----|--------------|-------|----------------------|

Safety Data Sheet

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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.