SAFETY DATA SHEET



1. Identification

Product identifier	Colistin Sulfate	
Other means of identification		
Catalog number	1148001	
CAS number	1264-72-8	
Synonyms	Polymyxin E sulfate	
Chemical name	Colistin sulfate	
Recommended use	Specified quality tests and a	issay use only.
Recommended restrictions	Not for use as a drug. Not for	or administration to humans or animals.
Manufacturer/Importer/Supplier/	Distributor information	
Manufacturer		
Company name	U. S. Pharmacopeia	
Address	12601 Twinbrook Parkway	
	Rockville	
	MD 20852-1790	
	United States	
Telephone	RS Technical Services	301-816-8129
Website	www.usp.org	
E-mail	RSTECH@usp.org	
Emergency phone number	CHEMTREC within US & Canada	1-800-424-9300
	CHEMTREC outside US &	+1 703-527-3887
	Canada	
2. Hazard(s) identification		
Physical hazards	Not classified.	
Health hazards	Acute toxicity, oral	Category 3
Environmental hazards	Not classified.	
OSHA defined hazards	Not classified.	
Label elements		
	Auto	
	Carelo I	
Signal word	Danger	
Hazard statement	Toxic if swallowed.	
Precautionary statement		
Prevention	Wash thoroughly after handling.	
Response	If swallowed: Immediately call a poison center/doctor. Rinse mouth.	
Storage	Store locked up.	
Disposal	Dispose of contents/container in accordance with local/regional/national/international regulations.	
Hazard(s) not otherwise classified (HNOC)	None known.	
Supplemental information	Pharmacologically active material.	

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Colistin Sulfate	Polymyxin E sulfate	1264-72-8	100
4. First-aid measures			
Inhalation	Move to fresh air. Call a physician if symptom	is develop or persist.	
Skin contact	Rinse skin with water/shower. Get medical attention if irritation develops and persists.		
Eye contact	Rinse with water. Get medical attention if irritation develops and persists.		
Ingestion	IF SWALLOWED: Immediately call a POISON CENTER or doctor/physician. Rinse mouth thoroughly. Do not induce vomiting without advice from poison control center. If vomiting occurs, keep head low so that stomach content doesn't get into the lungs.		
Most important symptoms/effects, acute and delayed	Pharmacologically active material. Occupational exposure may cause physiological effects.		
Indication of immediate medical attention and special treatment needed	Provide general supportive measures and tre	at symptomatically.	
General information	Remove from exposure. Remove contaminate an occupational health physician or other lice chemical exposures. In the United States, the 1-800-222-1222. If person is not breathing, gi oxygen if available. Persons developing serio receive immediate medical attention.	nsed health-care provider fam national poison control cente ve artificial respiration. If brea	iliar with workplace r phone number is thing is difficult, give
5. Fire-fighting measures			
Suitable extinguishing media	Water. Foam. Dry chemical or CO2. Use fire- materials.	extinguishing media appropria	te for surrounding
Unsuitable extinguishing media	None known.		
Specific hazards arising from the chemical	No unusual fire or explosion hazards noted.		
Special protective equipment and precautions for firefighters	Wear suitable protective equipment.		
Fire fighting equipment/instructions	Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area. Firefighters should use self-contained breathing equipment and protective clothing.		
Specific methods	Use standard firefighting procedures and con	sider the hazards of other invo	lved materials.
General fire hazards	No unusual fire or explosion hazards noted.		
6. Accidental release meas	sures		
Personal precautions, protective equipment and emergency procedures	Keep unnecessary personnel away. Wear ap inhalation of dust from the spilled material. Do unless wearing appropriate protective clothing protection, see section 8 of the SDS.	o not touch damaged containe	rs or spilled material
Methods and materials for containment and cleaning up	For waste disposal, see section 13 of the SD Sweep up or vacuum up spillage and collect i thoroughly to remove residual contamination.	in suitable container for dispos	
Environmental precautions	Avoid discharge into drains, water courses or		
7. Handling and storage			
Precautions for safe handling	As a general rule, when handling USP Refere dust, mists, and/or vapors associated with the suitable detergent or solvent after use. After r thoroughly. Select and use containment devic risk assessment of material potency and expo	e material. Clean equipment an removing gloves, wash hands ces and personal protective eq	nd work surfaces with and other exposed ski
Conditions for safe storage, including any incompatibilities	Store in tight container as defined in the USP label instructions to ensure product integrity.	-NF. This material should be h	andled and stored pe
8. Exposure controls/pers	onal protection		

8. Exposure controls/personal protection

Occupational exposure limits	No exposure limits noted for ingredient(s).
Biological limit values	No biological exposure limits noted for the ingredient(s).

Appropriate engineering controls	For laboratory operations, use local exhaust ventilation or a ventilated enclosure for high energy operations such as particle sizing. Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for solutions and slurries while being transferred.
Individual protection measures	s, such as personal protective equipment
Eye/face protection	Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary. Base the choice of protection on the job activity and potential for contact with eyes or face. An emergency eye wash station should be available.
Skin protection	
Hand protection	Wear nitrile or other impervious gloves if skin contact is possible. When the material is dissolved or suspended in an organic solvent, wear gloves that provide protection against the solvent.
Other	Train employees in proper gowning and degowning practices. Wear lab coat. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.
Respiratory protection	Respirators are generally not required for laboratory operations. Use a tight-fitting full-face respirator with HEPA filters for spill cleanup. Chose respiratory protection appropriate to the task and the level of existing engineering controls.
Thermal hazards	Wear appropriate thermal protective clothing, when necessary.
General hygiene considerations	Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance	Appearance descriptions are general information and not specific to any USP lot.
Physical state	Solid.
Form	Powder.
Color	White. Light yellow.
Odor	Odorless.
Odor threshold	Not available.
рН	Not available.
Melting point/freezing point	392 - 428 °F (200 - 220 °C) (decomposes)
Initial boiling point and boiling range	Not available.
Flash point	Not available.
Evaporation rate	Not available.
Flammability (solid, gas)	Not available.
Upper/lower flammability or exp	losive limits
Flammability limit - lower (%)	Not available.
Flammability limit - upper (%)	Not available.
Explosive limit - lower (%)	Not available.
Explosive limit - upper (%)	Not available.
Vapor pressure	Not available.
Vapor density	Not available.
Relative density	Not available.
Solubility(ies)	
Solubility (water)	Freely soluble.
Auto-ignition temperature	Not available.
Decomposition temperature	Not available.
Viscosity	Not available.
Other information	
Chemical family	Cyclic polypeptide.
Molecular formula	Colistin A: C53H100N16O13 . xH2SO4; Colistin B: C52H98N16O13 . xH2SO4

10. Stability and reactivity

Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
Chemical stability	Material is stable under normal conditions.
Possibility of hazardous reactions	No dangerous reaction known under conditions of normal use.
Conditions to avoid	Contact with incompatible materials.
Incompatible materials	Oxidizing agents.
Hazardous decomposition products	Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions. SOx. NOx.

11. Toxicological information

Information on likely routes of exposure

Inhalation	Knowledge about health hazard is incomplete.
Skin contact	Knowledge about health hazard is incomplete.
Eye contact	Knowledge about health hazard is incomplete.
Ingestion	Toxic if swallowed.
Symptoms related to the physical, chemical, and toxicological characteristics	Tingling and prickling sensations. Dizziness. Slurred speech. Reduced urine output. Blurred vision. Gastrointestinal disturbances.

Information on toxicological effects

Acute toxicity	Toxic if swallowed.	
Product	Species	Test Results
Colistin Sulfate (CAS 1264-72-8)		
Oral		
LD50	Mouse	720 mg/kg
	Rat	121 mg/kg
Skin corrosion/irritation	Knowledge about health hazard is incomplete.	
Serious eye damage/eye irritation	Knowledge about health hazard is incomplete.	
Respiratory or skin sensitization	n	
Respiratory sensitization	Knowledge about health hazard is incomplete.	
Skin sensitization	Knowledge about health hazard is incomplete.	
Germ cell mutagenicity	Knowledge about mutagenicity is incomplete.	
Mutagenicity Ames test Result: Negative. Micronucleus test Result: Negative. Mutagenicity: Gene Result: Negative.	mutation in mammalian cells	
Carcinogenicity	Knowledge about carcinogenicity is incomplete.	
IARC Monographs. Overall	Evaluation of Carcinogenicity	
Not listed. OSHA Specifically Regulat	ed Substances (29 CFR 1910.1001-1050)	
Not regulated.		
	ogram (NTP) Report on Carcinogens	
Not listed.		
Reproductive toxicity	Knowledge about health hazard is incomplete.	
Specific target organ toxicity - single exposure	Knowledge about health hazard is incomplete.	
Specific target organ toxicity - repeated exposure	Knowledge about health hazard is incomplete.	
Aspiration hazard	Based on available data, the classification criteria	are not met.
Material name: Caliptin Sulfate		105.050

Further information Pharmacologically active material. Occupational exposure may cause physiological effects.

12. Ecological information

Ecotoxicity	The product is not classified as environmentally hazardous. However, this does not exclude the possibility that large or frequent spills can have a harmful or damaging effect on the environment.
Persistence and degradability	No data is available on the degradability of this product.
Bioaccumulative potential	No data available.
Mobility in soil	No data available.
Other adverse effects	No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation potential, endocrine disruption, global warming potential) are expected from this component.

13. Disposal considerations

Disposal instructions	Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the user of the product to determine, at the time of disposal, whether the product meets RCRA criteria for hazardous waste.
Local disposal regulations	Dispose in accordance with all applicable regulations.
Hazardous waste code	The waste code should be assigned in discussion between the user, the producer and the waste disposal company.
Waste from residues / unused products	Empty containers or liners may retain some product residues. This material and its container must be disposed of in a safe manner (see: Disposal instructions).
Contaminated packaging	Since emptied containers may retain product residue, follow label warnings even after container is emptied.

14. Transport information

DOT

DOT	
UN number	UN2811
UN proper shipping name	Toxic solid, organic, n.o.s. (Colistin Sulfate)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	111
ΙΑΤΑ	
UN number	UN2811
UN proper shipping name	Toxic solid, organic, n.o.s. (Colistin Sulfate)
Transport hazard class(es)	
Class	6.1
Subsidiary risk	-
Packing group	III
Other information	
Passenger and cargo	Allowed with restrictions.
aircraft	
Cargo aircraft only	Allowed with restrictions.
Transport in bulk according to	Not applicable.
Annex II of MARPOL 73/78 and	
the IBC Code	

DOT; IATA



General information

It is the shipper's responsibility to determine the correct transport classification at the time of shipment.

15. Regulatory information

15. Regulatory mormation	1	
US federal regulations	This product is a "Hazardous Chemical" as defined by the OSHA Hazar Standard, 29 CFR 1910.1200.	rd Communication
TSCA Section 12(b) Export	Notification (40 CFR 707, Subpt. D)	
Not regulated. CERCLA Hazardous Substa Not listed.	nce List (40 CFR 302.4)	
SARA 304 Emergency relea	se notification	
Not regulated.		
OSHA Specifically Regulate	d Substances (29 CFR 1910.1001-1050)	
Not regulated.		
	authorization Act of 1986 (SARA)	
Hazard categories	Immediate Hazard - Yes Delayed Hazard - No Fire Hazard - No Pressure Hazard - No Reactivity Hazard - No	
SARA 302 Extremely hazard	lous substance	
Not listed.		
SARA 311/312 Hazardous chemical	Yes	
SARA 313 (TRI reporting) Not regulated.		
Other federal regulations		
Clean Air Act (CAA) Section	112 Hazardous Air Pollutants (HAPs) List	
Not regulated.		
	112(r) Accidental Release Prevention (40 CFR 68.130)	
Not regulated.		
Safe Drinking Water Act (SDWA)	Not regulated.	
US state regulations	California Safe Drinking Water and Toxic Enforcement Act of 1986 (Pro is not known to contain any chemicals currently listed as carcinogens o	
International Inventories		
Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	Yes
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	Yes
United States & Puerto Rico	Toxic Substances Control Act (TSCA) Inventory	No
	nents of this product comply with the inventory requirements administered by the g components of the product are not listed or exempt from listing on the inventory a	
16. Other information, incl	uding date of preparation or last revision	

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Issue date	11-03-2003
Revision date	09-21-2018
Version #	06

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