

SAFETY DATA SHEET

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

1.1 PRODUCT IDENTIFIER

Product name: Colistimethate Sodium vials / CMS vials
Product Formulation Name: Colistimethate Sodium vials
Generic Name: Pharmaceutical product
CAS# : 8068-28-8
EINECS# : 232-516-9
REACH reg.# : This mixture is a medicinal product according to Directive 2001/83/EC. Reach does not apply to medicinal products, and by this there is not required to make REACH registrations, SDS or CLP classification for this mixture.

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

Antibiotic

1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Xellia Pharmaceuticals ApS
Dalslandsgade 11
2300 Copenhagen S
Denmark
Responsible person for the safety data sheet (e-mail): sales@xellia.com

1.4 EMERGENCY TELEPHONE NUMBER

Xellia: 32 64 5500 in Denmark
Xellia: + 45 32 64 5500 outside of Denmark
INFOTRAC 800 535 5053
Poison Control Center (USA): 877 800 5553
CANUTEC (Canadian Transportation): 613 996 6666
CHEMTREC (USA Transportation): 800 424 9300
UN #: No applicable information found.

COMMENTS: To the best of our knowledge, this SDS conforms to the requirements of USA OSHA 29 CFR 1910.1200, 1907/2006/EC and Canadian Hazardous Products Act. You are urged to consider laws and regulations applicable to your state and country.

SECTION 2: HAZARDS IDENTIFICATION

2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

CLP: None required.

2.2 LABEL ELEMENTS:

None.

2.3 OTHER HAZARDS:

None known.

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

Emergency Overview

This is a medicinal product that may affect body functions. When inside vials the hazard is considered negligible.

SECTION 3: Composition/information on ingredients

3.1 SUBSTANCES:

Chemical Name	Weight %	CAS#	EINECS#	INDEX#	REACH reg.#
Colistimethate Sodium	100	8068-28-8	232-516-9	None	None

Comments: Product composition ranges shown are typical values for health, safety and environmental use and are not intended as specifications.

SECTION 4: First aid measures

4.1 DESCRIPTION OF FIRST AID MEASURES:

Eye contact: Flush eyes for 15 minutes with plenty of water. Get medical attention immediately.

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.

Ingestion: 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.

Inhalation: Move individual to fresh air. Get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

Medical Attention: Seek emergency medical attention if you think you have used too much of this medicine. Be aware for drug interactions.

4.2 MOST IMPORTANT SYMPTOMS AND EFFECTS, BOTH ACUTE AND DELAYED:

Eyes, Skin and Inhalation: None expected.

Ingestion Exposure: None expected.

Carcinogenicity: Testing not conducted.

Mutagenicity: Testing not conducted.

REPRODUCTIVE TOXICITY:

Reproductive Effects: No effects in rats.

Teratogenic Effects: Colistimethate is teratogenic in rabbits but not rats. FDA Pregnancy Category C.

SENSITIZATION:

Allergic skin rash has been reported.

MEDICAL CONDITIONS AGGRAVATED:

Allergy to colistimethate and poor kidney function.

4.3 INDICATIONS 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.

SECTION 5: Firefighting measures

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:

No applicable information identified. Use water spray to cool fire-exposed containers and structures.

SECTION 6: 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:

Water spill: Do not empty into drains.

Land spill: Vacuum material with appropriate dust collection in place. Be aware of potential for dust explosion when using electrical equipment. If a vacuum is not available, lightly mist material and remove by sweeping or wet wiping. Wear appropriate equipment including eye protection, to avoid exposure.

Release notes: If the spill could potentially enter any waterway, including intermittent dry creeks, contact the local authorities. In the USA, contact the USA Coast Guard National Response Center toll free 800 424 8802.

6.3 METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP:

Contain dry material by lightly misting with water, followed by sweeping carefully so as not to generate dust, or vacuuming. Ensure the vacuum is fitted with an appropriate dust filter so dust is not re-introduced into the air. Be aware of dust explosion when using electrical equipment.

6.4 REFERENCES TO OTHER SECTIONS:

See section 1 for emergency contact information, section 8 for personal protective equipment details, and section 13 for disposal information.

SECTION 7: Handling and storage

7.1 PRECAUTIONS FOR SAFE HANDLING:

For large quantities: If vials are opened or damaged, engineering controls are recommended to ensure adequate ventilation. 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.

For small quantities: Keep dry and away from sources of ignition. Keep the vials tightly closed when not in use.

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 in unopened sales container.

7.3 SPECIFIC END USES:

See section 1.

SECTION 8: Exposure controls/personal protection

8.1 CONTROL PARAMETERS:

When inside vials the hazard is considered negligible. If opened for some purpose then follow 8.2 advices.

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.

Personal protective equipment:

Eyes and face:

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

Skin:

Chemical resistant gloves (nitrile or latex) and body covering.

Respiratory:

Use an approved respirator suitable to provide level of protection required.

Comments: This product is not specifically listed by OSHA or ECHA as hazardous.

SECTION 9: Physical and chemical properties

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES:

Physical state:	Solid.
Appearance:	White to slightly yellow fine powder in vials.
Color:	White to slightly yellow.
Odor:	Odorless.
Odor threshold:	Not relevant.
pH:	No applicable information found.
Vapour pressure:	No applicable information found.
Vapour density:	No applicable information found.
Evaporation rate:	No applicable information found.
Freezing point:	Not applicable.
Melting point:	No applicable information found.
Boiling point:	No applicable information found as this is a powder.
Flash point:	No applicable information found.
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:	Freely soluble.
Density:	No applicable information found.
Specific gravity:	No applicable information found.
Viscosity:	No applicable information found.

Explosive properties: No applicable information found.
Oxidising properties: No applicable information found.
Coefficient of oil and water: No applicable information found.

9.2 OTHER INFORMATION:

None relevant.

SECTION 10: Stability and reactivity

10.1 REACTIVITY: No applicable information found.
10.2 CHEMICAL STABILITY: Stable at normal temperatures and pressures.
10.3 POSSIBILITY OF HAZARDOUS REACTIONS: No applicable information found.
10.4 CONDITIONS TO AVOID: Keep away from ignition sources and heat.
10.5 INCOMPATIBLE MATERIALS: No applicable information found.
10.6 HAZARDOUS DECOMPOSITION PRODUCTS: Nitrogen oxides, carbon monoxide, oxides of sulfur, irritating and toxic fumes and gases, carbon dioxide.

SECTION 11: Toxicological information

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS:

Acute dermal LD₅₀: Not determined.
Acute oral LD₅₀: 5450 mg/kg (rat). This is applicable for Colistimethate API.
Acute inhalation LC₅₀: Not determined.
Eye effects: Not determined.
Skin effects: Not determined.
Sensitization: Allergic skin rash has been reported.
Target organ: Nervous system (tingling or numb sensation, lethargy, confusion, dizziness, ataxia, nystagmus, speech disorder and shortness of breath); kidney (decreased urine output, increase in serum BUN and creatinine); and skin (rash).
Carcinogenicity: Not determined.
Listed by IARC: No **Listed by NTP:** No **Listed by OSHA:** No
Mutagenicity: Not determined.
Reproductive effects: No effects in rats.
Teratogenic effects: Teratogenic in rabbits but not rats. FDA Pregnancy Category C.

SECTION 12: Ecological information

12.1 TOXICITY: No applicable information found.
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 RESULTS OF PBT AND vPvB ASSESSMENT: The substance is not considered PBT/vPvB according to criteria in Annex XIII.
12.6 OTHER ADVERSE EFFECTS: The substance is possibly harmful for the aquatic environment, due to its antibiotic properties.

SECTION 13: Disposal considerations

13.1 WASTE TREATMENT METHODS:

Disposal (includes Spills, Empty Containers): **Dispose of any cleanup materials and waste residue according to applicable laws and regulations.**

SECTION 14: Transport information

UN NUMBER: Not regulated.
UN PROPER SHIPPING NAME: Not relevant.
TRANSPORT HAZARD CLASS(ES): Not relevant.
PACKING GROUP: Not relevant.
ENVIRONMENTAL HAZARDS: None.
SPECIAL PRECAUTIONS FOR USER: None.
TRANSPORT IN BULK ACCORDING TO ANNEX II MARPOL 73/78 AND THE IBC CODE: Not relevant.

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.

SECTION 15: Regulatory information

15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATION/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE:

This section contains selected regulatory information for possible use by Xellia Pharmaceuticals. This section is not intended to be a complete listing of all applicable regulations. You are urged to consider laws and regulations applicable to your state and country.

EUROPEAN COMMUNITY

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH),

Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work:

Not regulated. However, it is recommended that the product is not used by persons under 18 years of age.

Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding:

Not regulated. However, it is recommended, that the employer assess the working conditions and, if there is any risk to the safety or health and any effects on the pregnancy or breastfeeding of workers, take the necessary measures to adjust the working conditions.

Implementation of directive 2001/82/EC of the European Parliament and of the council of 6 November 2001 in the Community code relating to veterinary medical products:

Denmark: The Danish Medicines Agency (Lægemiddelstyrelsen) must be notified that this substance is produced, imported, exported, stored, sold, delivered, packed, possessed or in other ways handled in Denmark (Bekendtgørelse nr. 1226 af 7. December 2005 om omgang med visse stoffer og produkter hvis indhold kan anvendes som lægemidler til dyr.).

For other countries: Please contact national authorities regarding notification of the substance.

UNITED STATES FEDERAL REGULATIONS

Superfund Amendments and Reauthorization Act (SARA) Title III 311/312 hazard categories:

Fire: No **Pressure generating:** No **Reactivity:** No **Acute:** No **Chronic:** No

313 Reportable Ingredients: Not listed.

Title III notes:

Comprehensive Response, Compensation, and Liability Act (CERCLA)

CERCLA RQ: Not listed

Toxic Substances Control Act (TSCA)

TSCA Regulatory: Not listed.

National Response Center: US Coast Guard National Center Response Telephone number is 800 424 8802.

UNITED STATES STATE REGULATIONS

California Proposition 65: Not listed.

CANADA

Workplace Hazardous Material Information System (WHMIS) hazard symbol and classification

WHMIS Controlled: Not regulated.

Canadian Environmental Protection Act: Not listed.

15.2 CHEMICAL SAFETY ASSESSMENT:

No CSR.

SECTION 16: Other information'

Reason for issue: EC regulation, REACH and CLP

Contact information: See Section 1

Revision summary: 1-16

	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.

Disclaimer: Information given herein is offered in good faith as accurate, but without guarantee. Conditions of use and suitability of the product for particular uses are beyond our control; all risks of use of the product are therefore assumed by the user. Nothing is intended as a recommendation for uses that infringe valid patents or as extending license under valid patents. Appropriate warnings and safe handling procedures should be provided to handlers and users.

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)