

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 Powder for solution for injection or infusion

CAS #: 8068-28-8

EC/List #: 232-516-9

INDEX #: Not listed

REACH reg. #: Not registered, exempted

1.2. Relevant identified uses of the substance or mixture and uses advised against

Product Use: Pharmaceutical product used as antibiotic agent

Synonyms: CMS, Colistimethate sodium dry-filled vials

1.3. Details of the supplier of the safety data sheet

Manufacturer & Distribution

Xellia Pharmaceuticals ApS

Dalslandsgade 11

2300 Copenhagen S

Denmark

+45 3264 5500

Responsible person for the safety data sheet (e-mail): sales@xellia.com

1.4. Emergency telephone number

Poison Control Center (USA): +1 877 800 5553

CHEMTREC (USA Transportation): +1 800 424 9300

CANUTREC (Canadian Transportation): +1 613 996 6666

UN #: <http://apps.who.int/poisoncentres/>

SECTION 2: Hazards identification

2.1. Classification of the substance or mixture

Reproductive Toxicity - Category 2; Reproductive toxicity, effects on or via lactation – Additional Category

2.2. Label elements



WARNING

H361: Suspected of damaging fertility or the unborn child.

H362: May cause harm to breast-fed children.

P203: Obtain, read and follow all safety instructions before use.

P280: Wear protective gloves/protective clothing/eye protection/face protection/hearing protection/
 P318: if exposed or concerned, get medical advice.

P405: Store locked up.
 P501: Dispose of contents/container appropriately.

2.3. Other hazards

PBT/vPvB: The substance is not considered PBT/vPvB according to criteria in Annex XIII, neither has properties of endocrine disruption.

SECTION 3: Composition/information on ingredients

3.1. Substances

Active component	CAS #	EC/List #
Colistimethate Sodium	8068-28-8	232-516-9

Comments: Not Applicable.

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.

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

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

Medical Conditions Aggravated by Exposure: None

4.3. Indication 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 center, treat symptomatically.

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: Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.

Unsuitable extinguishing media: None

Specific methods: Not available

5.3. Advice for firefighters

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

SECTION 6: Accidental release measures

6.1. Personal precautions, protective equipment and emergency procedures

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.

6.3. Methods and material 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 the potential for dust explosion when using electrical equipment.

6.4. Reference 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: Engineering controls are recommended to ensure adequate ventilation such that exposures do not exceed TWA for an eight-hour exposure. 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 container 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

Store securely, inaccessible for unauthorized persons. Keep dry and away from sources of ignition. Store below -20°C (-4°F) in original, unopened package or container.

7.3. Specific end use(s)

See section 1.

SECTION 8: Exposure controls/personal protection

8.1. Control parameters

OSHA'S hazardous components (29 CFR 1910.1020) EXPOSURE LIMITS AND GUIDELINES

	<u>OSHA PEL</u>		<u>ACGIH TLV</u>		<u>OTHER OEL (TWA)</u>	
	ppm	mg/m ³	ppm	mg/m ³	ppm	mg/m ³
Colistimethate Sodium (CAS # 8068-28-8)	N/A	N/A	N/A	N/A	N/A	0.28

OEL for the substance: 0.28 mg/m³ in OEL Fastrack

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 material may cause sensitization or an allergic response with minimal exposure. Under conditions of overexposure, the material may be hazardous.

SECTION 9: Physical and chemical properties

9.1. Information on basic physical and chemical properties

Physical state:	Solid
Colour:	White to slightly yellow
Odour:	Odorless
Melting point/freezing point:	Not available
Boiling point or initial boiling and boiling range:	not applicable for solids
Flammability:	Not available
Lower and upper explosion limit:	Not available
Flash point:	not applicable for solids
Auto-ignition temperature:	Not available
Decomposition temperature:	Not available
pH:	6.5 – 8.5 (1% solution)
Kinematic viscosity:	not applicable for solids
Solubility:	soluble in water
Partition coefficient n-octanol/water (log value):	Not available
Vapour pressure:	not applicable for solids
Density and/or relative density:	Not available
Relative vapour density:	not applicable for solids
Particle characteristics:	Not available

9.2. Other information

Not available.

SECTION 10: Stability and reactivity

10.1. Reactivity

No data available.

10.2. Chemical stability

Stable under recommended storage conditions.

10.3. Possibility of hazardous reactions

Hazardous polymerization has not been reported.

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 carbon dioxide.

SECTION 11: Toxicological information

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

Acute dermal LD50: Not available

Acute oral LD50: 5450 mg/kg (rat)

Acute inhalation LC50: Not available

Based on available data, the classification criteria are not met.

Eye effects: Based on available data, the classification criteria are not met.

Skin effects: Based on available data, the classification criteria are not met.

Sensitization: Allergic skin rash has been reported. Based on available data, the classification criteria are not met.

Target organ: Nervous system (tingling or numb sensation, lethargy, confusion, dizziness, ataxia, nystagmus, speech disorder and shortness of breath); kidney (decreased urine output); diarrhea, muscle paralysis and kidney toxicity, respiratory failure and skin (rash).

Carcinogenicity: Based on available data, the classification criteria are not met.

Listed by IARC: No Listed by NTP: No Listed by OSHA: No

Mutagenicity: Based on available data, the classification criteria are not met.

Reproductive effects: Teratogenic in rabbits but not rats. FDA Pregnancy Category C.

11.2. Information on other hazards

No data available

SECTION 12: Ecological information

12.1. Toxicity

No applicable information found. Releases to the environment should be avoided.

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. Endocrine disrupting properties

No such properties are known to the substance.

12.7. 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

Do not empty into drain. Dispose of any cleanup materials and waste residue according to applicable laws and regulations.

SECTION 14: Transport information

14.1. UN Number or ID number

Not regulated.

14.2. UN proper shipping name

Not regulated.

14.3. Transport hazard class(es)

Not regulated.

14.4. Packing group

Not regulated.

14.5. Environmental hazards

Not regulated.

14.6. Special precautions for user

Not regulated.

14.7. Maritime transport in bulk according to IMO instruments

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 available.

SECTION 15: Regulatory information

15.1. Safety, health, and environmental regulations/legislation specific for the substance or mixture

EUROPEAN UNION

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

Must not be 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:

The employer shall 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: Exempt

National Response Center: US Coast Guard National Center Response Telephone

+1 800 424 8802.

UNITED STATES STATE REGULATIONS

California Proposition 65: This product does not contain chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

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 is compiled because the substance is exempted.

SECTION 16: Other information⁹

Reason for issue: Update to include 2020/878 EU Commission regulation. Updated OEL

Contact Information: See Section 1.

Revision summary: Forth issue with subversion: 4.1.

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