

# MATERIAL SAFETY DATA SHEET

## **Colistimethate for Injection, USP**

**Paddock Laboratories, Inc.**  
**3940 Quebec Avenue North**  
**Minneapolis, MN 55427**

**Emergency Assistance:**  
**CHEMTREC® (24-hour) 1-800-424-9300**

Tel: (763) 546-4676

Paddock Technical Assistance: 1-800-328-5113

Creation Date: 21 December 2004

Revision Date: 21 December 2004

### **SECTION 1: PRODUCT IDENTIFICATION**

PRODUCT NAME: Colistimethate for Injection, USP  
COMMON NAME: Colistimethate Sodium for Injection  
CHEMICAL FORMULA:  $C_{58}H_{105}N_{16}Na_5O_{28}S_5$   
CHEMICAL FAMILY: Polypeptide Antibiotic

### **SECTION 2: COMPOSITION AND INGREDIENTS**

CHEMICAL NAME	CAS#	%	OSHA PEL	ACGIH TLV	IDLH
Colistimethate Sodium	8068-28-8	7%	NE	NE	NE

NE = Not Established

### **SECTION 3: HAZARDS IDENTIFICATION**

**EMERGENCY OVERVIEW:** No occupational hazard labels have been assigned to this material.

Routes of Entry: Inhalation: Possible  
Absorption: Unlikely  
Ingestion: Possible

Skin Exposure: No data available on the adverse effects associated with skin contact.

Eye Exposure: No data available on the adverse effects associated with eye contact.

Inhalation: Inhalation may cause nervous system effects (tingling of the extremities and tongue, dizziness, slurred speech) and gastrointestinal disturbances. Exposure may cause allergic reactions (skin rash) in sensitive individuals.

Ingestion: Ingestion may cause nervous system effects (tingling of the extremities, dizziness, slurred speech) and gastrointestinal disturbances. Exposure may cause allergic reactions (skin rash) in sensitive individuals.

Miscellaneous Information: Respiratory arrest has been reported following therapeutic administration of this drug. There are reports of birth defects in experimental animals at very high doses. However, these effects are not expected to be a potential result of occupational exposure to the finished product.

**SECTION 4: FIRST AID MEASURES**

- Skin Exposure: Remove contaminated clothing. Promptly wash exposed skin areas with soapy water. Seek medical attention if adverse symptoms develop.
- Eye Exposure: In case of contact, immediately flush eyes with water. Hold eyelids open to ensure adequate flushing. Seek medical attention.
- Inhalation: Remove victim to fresh air. Seek medical attention.
- Ingestion: Administer 1-2 glasses of milk or water to dilute ingested material. Seek medical attention.

**SECTION 5: FIRE / EXPLOSION HAZARDS & FIRE-FIGHTING MEASURES**

Flash Point (Method Used): NA

Flammable Limits: NE                      Lower: NA    Upper: NA

Fire Extinguishing Equipment: Use extinguishing agent suitable for type of surrounding fire.

Water Spray: OK    Carbon Dioxide: OK  
Foam: OK            Dry Chemical: OK

Fire and Explosion Hazards: Minimal fire hazard under normal conditions of use.

Special Fire Fighting Procedures: For fires beyond the incipient stage, emergency responders in the immediate hazard area should wear bunker gear. When the potential chemical hazard is unknown, in enclosed or confined spaces, or when explicitly required by the DOT *Emergency Response Guidebook*, a self-contained breathing apparatus should be worn. In addition, wear other appropriate protective equipment as conditions warrant (see Section 8). Isolate immediate hazard area and keep unauthorized personnel out. Move undamaged containers from immediate hazard area if it can be done with minimal risk. Cool equipment exposed to fire with water, if it can be done with minimal risk. Small fires in the beginning stages may be extinguished with portable, hand-held fire extinguishers. Avoid exposure to the material, injury from broken containers, and inhalation of smoke. Larger fires require the assistance of professional firefighters.

Combustion Products: Thermal decomposition products may include oxides of carbon and nitrogen (smoke). Avoid inhalation.

NE = Not Established

NA= Not Applicable

**SECTION 6: ACCIDENTAL RELEASE MEASURES**

Spill and Leak Response: Clean up crews must wear appropriate protective equipment including respiratory, skin, and eye/face protection. Confine the spill and remove incompatible materials and ignition sources. Isolate the area to keep out unnecessary and unprotected personnel. Provide adequate ventilation and absorb liquid with an inert material (i.e. dry sand or vermiculite). Place waste in an appropriate container for future disposal. Use care in clean up to prevent exposure to the material and injury from broken containers. Wash all contaminated surfaces with soap and water.

Release to Water: Refer to local water authority. Comply with local, state, and federal regulations.

<b>SECTION 7: HANDLING AND STORAGE</b>
--

Work and Hygiene Practices: As with all chemicals, avoid getting this product ON YOU or IN YOU. Wash hands before eating, drinking, smoking or using toilet facilities. Wear safety glasses. For larger spills, additional PPE and respiratory protection may be needed such as chemical protective coveralls, boots, double gloves (neoprene/nitrile), and self-contained breathing apparatus (SCBA).

Other precautions: Store in a cool, well ventilated area away from heat, sparks, open flame and incompatible materials. Store in suitable labeled containers kept closed and protected from damage. Have emergency equipment (for fires, spills, etc.) readily available.

<b>SECTION 8: EXPOSURE CONTROLS / PERSONAL PROTECTION</b>
---

Ventilation and Engineering Controls: Handle in a well-ventilated area. None required under normal conditions of use.

Respiratory Protection: Under normal use, respirators are not required. For large spills, a respirator may be required. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard 29 CFR 1910.134.

Eye /Face Protection: No face protection required under normal conditions of use. Although the risk from eye exposure is minimal, prudence recommends the use of safety glasses.

Skin Protection: No skin protection is required under normal conditions of use.

Product Preparation Instructions for Medical Personnel: Follow standard procedure for handling pharmaceutical materials and recommendations presented on the Package Insert.

Manufacturing or dust/mist-producing operations may require the use of engineering controls or personal protective equipment to minimize exposure to this material and/or ingredients. If unusual exposures are expected an industrial hygiene review of work practices and engineering controls is recommended.

Personal protective equipment listed above represents the minimum recommended protection. It is the responsibility of the local supervisor or safety administrator to ensure that adequate engineering controls, PPE, and handling procedures are being used.

<b>SECTION 9: PHYSICAL / CHEMICAL PROPERTIES</b>
--

Boiling Point:	ND	Vapor Pressure:	ND
Physical State:	Solid	Solubility in Water:	Soluble
		Solubility (other)	ND
/Freezing Point:	ND	pH:	6.5-7.5 after reconstitution
Appearance:	Dry, white to slightly yellow powder (before reconstitution); colorless to pale yellow solution (after reconstitution).		

ND = Not Determined

**SECTION 10: STABILITY AND REACTIVITY**

Stability:	Stable under normal conditions of use.
Incompatible Materials:	Not Determined
Hazardous Polymerization:	Will not occur under normal conditions of use.
Conditions to Avoid:	Keep away from incompatible materials, ignition sources and heat.

**SECTION 11: TOXICOLOGICAL INFORMATION**

Oral LD <sub>50</sub> Mouse intravenous:	739.0 mg/kg
Oral LD <sub>50</sub> Dog intravenous:	41.5 mg/kg

Toxicity Data: Colistimethate Sodium is an anti-infective agent with daily doses ranging from 150-350 mg, administered intravenously or intramuscularly. Although it is an unlabeled route of administration, this drug is also given by inhalation at doses of 1-2 million units (33-66 mg). Adverse effects associated with the therapeutic use of this drug include tingling of the extremities or of the tongue, muscle weakness, skin rash, GI disturbances, fever, dizziness, slurred speech, and respiratory arrest. High doses may also cause kidney failure, especially after long-term use.

Suspected Cancer Agent: This product has **NOT** been identified as a carcinogen by NTP, IARC or OSHA.

Irritancy of Product: During normal use of product no eye contact should occur.

Sensitization to the Product: Not Known.

Reproductive Toxicity Information: Pregnancy Category C: Colistimethate sodium given intramuscularly during organogenesis to rabbits at 4.15 and 9.3 mg/kg resulted in talipes varus in 2.6% and 2.9% of fetuses, respectively. These doses are 0.25 and 0.55 times the maximum daily human dose based on mg/m<sup>2</sup>. In addition, increased resorption occurred at 9.3 mg/kg. Colistimethate sodium was not teratogenic in rats at 4.15 or 9.3 mg/kg. These doses are 0.13 and 0.30 times the maximum daily human dose based on mg/m<sup>2</sup>. There are no adequate and well-controlled studies in pregnant women. Since colistimethate sodium is transferred across the placental barrier in humans, it should be used during pregnancy only if the potential benefit justifies the potential risk to the fetus.

Mutagenicity: ND

ACGIH Biological Exposure Indices: Currently there are no Biological Exposure Indices (BEIs) associated with the components of this product.

**SECTION 12: ECOLOGICAL INFORMATION**

Information is currently not available on the adverse environmental effects of this material. Handle in a manner to prevent spills or releases to the environment. Report spills as applicable under local, state, and federal regulations.

**SECTION 13: WASTE DISPOSAL**

Preparing Wastes for Disposal: Dispose of waste according to local, state, and federal guidelines.

**SECTION 14: TRANSPORTATION INFORMATION**

This material is not regulated for transportation by land, air or sea.

**SECTION 15: REGULATORY INFORMATION****U.S. REGULATIONS:**

SARA 313 listed: No

CERCLA listed: No

RCRA listed: No

Available information does not classify this material as hazardous under the regulations of any occupational or environmental health and safety agencies.

**SECTION 16: OTHER INFORMATION**

Available information does not classify this material as hazardous under the regulations of any occupational or environmental health and safety agencies.

**DEFINITIONS OF ABBREVIATIONS USED:**

ACGIH:	American Conference of Governmental Industry Hygienists
CAS:	Chemical Abstract Service
IARC:	International Agency for Research on Cancer
IDLH:	Immediately Dangerous to Life or Health Level
LC <sub>50</sub> :	Medial Lethal Concentration
LD <sub>50</sub> :	Medial Lethal Dose
MSHA:	Mine Safety and Health Administration
N/A:	Not Available
NIOSH:	National Institute for Occupational Safety and Health
NTP:	National Toxicology Program
OSHA:	Occupational Safety and Health Administration
PEL:	Permissible Exposure Limit
STEL:	Short Term Exposure Limit
TLV:	Threshold Limit Value
TWA:	Time Weighted Average

TO THE BEST OF OUR KNOWLEDGE THE INFORMATION CONTAINED HEREIN IS ACCURATE AS OF THE DATE HEREOF. ANY DETERMINATION AS TO THE SUITABILITY OF THE PRODUCT FOR ANY PARTICULAR PURPOSE, ITS SAFE USE OR DISPOSAL SHALL BE THE RESPONSIBILITY OF THE USER. THE INFORMATION CONTAINED HEREIN IS IN NO WAY INTENDED TO SUPPLEMENT, MODIFY OR SUPERSEDE THE INFORMATION PROVIDED IN THE PRODUCT PACKAGE INSERT WITH RESPECT TO THE USE OF THE PRODUCT FOR MEDICAL PURPOSES.