



MATERIAL SAFETY DATA SHEET

While we believe the information provided herein is accurate and current, JHP Pharmaceuticals makes no representation or warranties, either explained or implied, and assume no responsibility for any damage or injuries of any kind, which may result from use or reliance upon this information

SECTION 1	MATERIAL IDENTIFICATION
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PRODUCT NAME: Coly-Mycin[®] M Parenteral (sterile colistimethate sodium, USP) **DATE OF ISSUE:** 11/19/2008

FORMULA: Mixture **SUPERCEDES:** 4/24/2008 **REVISION:** 2.0

NDC #: 42023-107-01 150 mg colistin base, 10 ml SDV **SYNONYMS:** NA

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SECTION 2	INGREDIENT (S)
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CAS #	INGREDIENT NAME	OSHA PEL	ACGIH TLV	OTHER	LISTED AS CARCINOGEN
8068-28-8	Colistimethate Sodium	NA	NA	NA	NO

SECTION 3	HAZARD IDENTIFICATION
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HMIS Hazard Ratings:
Health Hazard = 1
Flammability = 1
Reactivity = 0
Other: None

Key: **4 = Severe**
 3 = Serious
 2 = Moderate
 1 = Slight
 0 = Minimal

POTENTIAL HEALTH EFFECTS:

INHALATION:
SHORT TERM EXPOSURE: Irritation, tingling sensation, dizziness, difficulty speaking, allergic reactions, rash
LONG TERM EXPOSURE: No information on significant adverse effects

SKIN CONTACT:
SHORT TERM EXPOSURE: Rash.
LONG TERM EXPOSURE: No information on adverse effects

SECTION 3**HAZARD IDENTIFICATION cont.****EYE CONTACT:**

SHORT TERM EXPOSURE: Possible irritation. Avoid contact with eyes.

LONG TERM EXPOSURE: Possible irritation. Avoid contact with eyes.

INGESTION:

SHORT TERM EXPOSURE: Gastrointestinal irritation, dizziness, tingling sensation, rash, itching, fever, difficulty speaking, weakness, difficulty breathing, kidney damage, allergic reactions

LONG TERM EXPOSURE: No information on significant adverse effects

SECTION 4**FIRST AID INFORMATION**

THERAPEUTIC CLASS: Antibiotic

EYES: Flush eyes with plenty of water for at least 15 minutes. Get immediate medical attention.

SKIN: Wash exposed skin with soap and water for at least 15 minutes while removing contaminated clothes and shoes. Get medical attention if needed. Thoroughly clean and dry contaminated clothing and shoes before reuse.

INHALATION: If adverse effects occur, remove to uncontaminated area. Give artificial respiration if not breathing. If breathing is difficult, oxygen should be administered by qualified personnel. Get immediate medical attention.

INGESTION: If large amount is swallowed, get medical attention.

SECTION 5**FIRE AND EXPLOSION DATA**

FLASH POINT AND METHOD: ND

EXTINGUISHING MEDIUM: CO₂ Dry Chem., foam, water spray.

SPECIAL FIRE PROCEDURES: Use self-contained breathing apparatus.

HAZARDOUS DECOMPOSITION OR COMBUSTION PRODUCTS: Thermal decomposition products or combustion: oxides of carbon, oxides of nitrogen

FIRE HAZARDS: ND

EXPLOSION HAZARDS: ND

SECTION 6**ACCIDENTAL RELEASE MEASURES****ACTION TO BE TAKEN IF MATERIAL IS RELEASED OR SPILLED:**

Stop leak if possible without personal risk. Small Spills: Absorb with sand or other non-combustible material. Collect spilled material in appropriate container for disposal.

SECTION 7**HANDLING AND STORAGE**

STORAGE: Store and handle in accordance with all current regulations and standards. Store between 15°C and 30°C. Avoid contact with light. Store in a cool, dry place. Keep container tightly closed and in a well-ventilated place. Protect from physical damage. See original container for storage recommendations. Keep separated from incompatible substances.

SECTION 8**SPECIAL PROTECTION INFORMATION**

VENTILATION: Use adequate ventilation. Ventilation equipment should be explosion-resistant if explosive concentrations of material are present. Ensure compliance with applicable exposure limits.

EYE PROTECTION: Wear splash resistant safety goggles. Provide an emergency eye wash fountain and quick drench shower in the immediate work area.

CLOTHING: Wear appropriate chemical resistant clothing.

GLOVES: Wear appropriate chemical resistant gloves.

RESPIRATOR: Under conditions of frequent use or heavy exposure, respiratory protection may be needed. Respiratory protection is ranked in order from minimum to maximum. Consider warning properties before use.

Any chemical cartridge respirator with appropriate organic vapor and particulate cartridges(s)

Any chemical cartridge respirator with a full face piece with appropriate organic vapor and particulate cartridge(s).

Any air-purifying respirator with a full face piece with appropriate organic vapor and particulate canister

For Unknown Concentrations or Immediately Dangerous to Life or Health-

Any supplied-air respirator with full face piece and operated in a pressure-demand or other positive –pressure mode in combination with a separate escape supply.

Any self-contained breathing apparatus with a full face piece.

SECTION 9**PHYSICAL AND CHEMICAL DATA**

PHYSICAL STATE: Solid

APPEARANCE: White to light yellow powder

CHARACTERISTIC ODOR: None

SPECIFIC GRAVITY: ND

SOLUBILITY:

pH (@ 25 C: 6.5 – 7.5

WATER: Soluble

SECTION 10**STABILITY AND REACTIVITY**

REACTIVITY: Stable at normal temperature and pressure

CONDITIONS TO AVOID: Avoid heat, flames, sparks and other sources of ignition. Avoid contact with incompatible materials.

INCOMPATIBLES: Oxidizing materials.

POLYMERIZATION: Will not polymerize.

SECTION 11**TOXICOLOGY****TOXICITY INFORMATION:**

The following information pertains to the ingredient(s) individually and not to the product as marked. Included will be any data which emphasize the potential effects that may occur with the occupational handling (by inhalation or by dermal or by ocular contact) of this product.

COLY-MYCIN® R PARENTERAL: May cross the placenta. May impair performance of tasks requiring alertness. Interactions with drugs may occur. This product may be administered by either intravenous or intramuscular routes. The toxicity and health effects are presumed to be essentially the same as those from parenteral administration.

COLISTIMETHATE SODIUM: Rat oral. LD₅₀; 5450 mg/kg. Slightly toxic by ingestion. Information on reproductive effects is available. May cross the placenta. May impair performance of tasks requiring alertness. Interactions with drugs may occur. This product may be administered by either intravenous or intramuscular routes. The toxicity and health effects are presumed to be essentially the same as those from parenteral administration.

SECTION 12**ECOLOGICAL INFORMATION**

Not available

SECTION 13**DISPOSAL**

WASTE DISPOSAL METHOD: Dispose of in accordance with local, state, and federal regulations or the authority having jurisdiction. Incineration in a permitted incinerator is the preferred disposal method.

SECTION 14**TRANSPORTATION****SHIPPING REQUIREMENTS AND LIMITATIONS**

PROPER SHIPPING NAME: NA **ID/UN NUMBER:** NA **CONTAINER SPECIFICATION:** NA

HAZARD CLASS: NA **LABEL:** NA **PACKAGING GROUP:** NA

SHIPPING LIMITATIONS: NA **MARKING:** NA **OTHER COMMENTS:** NA

U.S REGULATIONS:

CERCLA SECTIONS 102a/103 HAZARDOUS SUBSTANCES (40 CFR 302.4): Not regulated.

SARA TITLE III SECTIONS 302/304 EXTREMELY HAZARDOUS SUBSTANCES: Not regulated.

SARA TITLE III SECTIONS 311/312 HAZARDOUS CATEGORIES: Not regulated.

ACUTE: No

CHRONIC: No

FIRE: No

REACTIVE: No

SUDDEN RELEASE: No

SARA TITLE II SECTION 313: Not regulated.

OSHA PROCESS SAFETY: Not regulated.

STATE REGULATIONS:

California Proposition 65: Not regulated

NATIONAL INVENTORY STATUS:

U.S. INVENTORY (TSCA): This product is exempt

TSCA 12(b) EXPORT NOTIFICATION: Not listed.

NA – NOT APPLICABLE

ND – NO DATA FOUND

The information provided in this Material Safety Data Sheet has been compiled from our experience and the data presented in various technical publications. It is the user's responsibility to determine the suitability of this information for the adoption of safety precautions as may be necessary. We reserve the right to revise the Material Safety Data Sheets from time to time as new information becomes available. The user has the responsibility to contact the company to make sure the sheet is the latest one issued.