



**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**

**PRODUCT NAME:** Coly-Mycin® S Otic (colistin sulfate-neomycin sulfate-thomzonium bromide-hydrocortisone acetate otic suspension) **DATE OF ISSUE:** 4/24/2008

**FORMULA:** Mixture **SUPERCEDES:** N/A **REVISION:** 1.0

**NDC #:** 42023-108-01 Coly-Mycin® S Otic, 5mL Bottle with Dropper **SYNONYMS:** NA

**MANUFACTURING DIVISION:** JHP Pharmaceuticals, LLC. **ADDRESS:** 870 Parkdale Road Rochester, MI 48307 **PHONE :** Emergency: 248-656-5400 Medical Affairs: 866-923-2474

**SECTION 2 INGREDIENT (S)**

CAS #	INGREDIENT NAME	OSHA PEL	ACGIH TLV	OTHER	LISTED AS CARCINOGEN
1264-72-8	Colistin Sulfate	NA	NA	NA	NO
1405-10-3	Neomycin Sulfate	NA	NA	NA	NO
50-03-3	Hydrocortisone Acetate	NA	NA	NA	NO
NA	Thonzonium Bromide (surface-active agent) 0.050%	NA	NA	NA	NO

**SECTION 3 HAZARD IDENTIFICATION**

**POTENTIAL HEALTH EFFECTS:**

**INHALATION:**

**SHORT TERM EXPOSURE:** Significant adverse effects not expected during routine handling of product.

**LONG TERM EXPOSURE:** Significant adverse effects not expected during routine handling of product..

**SKIN CONTACT:**

**SHORT TERM EXPOSURE:** Possible irritation. Avoid contact with skin.

**LONG TERM EXPOSURE:** Possible irritation. Avoid contact with skin.

**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:** ND

**LONG TERM EXPOSURE:** ND

**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. 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:** CO<sub>2</sub> Dry Chem., foam, water spray.

**SPECIAL FIRE PROCEDURES:** Use self-contained breathing apparatus.

**HAZARDOUS DECOMPOSITION OR COMBUSTION PRODUCTS:** Oxides of carbon, nitrogen, and sulfur, HBr.

**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 2°C and 8°C. Avoid contact with light. See original container for storage recommendations. Keep separated from incompatible substances.

**SECTION 8****SPECIAL PROTECTION INFORMATION**

**VENTILATION:** Use adequate ventilation. 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:** Liquid

**APPEARANCE:** Aqueous suspension of white to off white solids which settle rapidly.

**CHARACTERISTIC ODOR:** ND

**SPECIFIC GRAVITY:** 1.106

**SOLUBILITY:**

**pH (@ 25 C):** 5.0

**WATER:** ND

**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.

**COLISTIN SULFATE:** Mouse oral LD<sub>50</sub>: 793 mg/kg; Rat S.C. LD<sub>50</sub>: 72.20 mg/kg; Pharmacotoxic signs seen in rat subcutaneous studies are dyspnea and cyanosis. Bronchial irritation may occur following inhalation. Not teratogenic or embryotoxic in mice and rats. Side effects seen in therapeutic use following parenteral administration include respiratory arrest, reversible nephrotoxicity, paresthesia, and itching or urticaria. The occurrence of these effects in the occupational setting is considered unlikely.

**NEOMYCIN SULFATE:** Rat S.C. LD<sub>50</sub>: 200mg/kg; Mouse S.C. LD<sub>50</sub>: 190 mg/kg; Mild skin irritant in human standard tests at 6mg/ 3 days – intermittent). May cause irreversible partial or total deafness. Has caused sensitization reactions in humans after therapeutic use. May also cause gastrointestinal effects such as nausea, vomiting, diarrhea, and malabsorption.

**HYDROCORTISONE ACETATE:** Mouse subcutaneous LD50: 45 mg/kg; Mouse I.P. LD50: 2300 mg/kg; mildly irritating in dermal rabbit studies

**SECTION 12****ECOLOGICAL INFORMATION**

Not available

**SECTION 13****DISPOSAL**

**WASTE DISPOSAL METHOD:** Due to the trace amount of mercury found in this product (0.001%); dispose of as a Hazardous Waste in accordance with local, state, and federal regulations or the authority having jurisdiction. Incineration in a permitted incinerator is the preferred disposal method, which solidification of incinerator residue and subsequent disposal at a permitted TSD facility.

**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: Yes

CHRONIC: Yes

FIRE: No

REACTIVE: No

SUDDEN RELEASE: Yes

**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.

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**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.