

# SAFETY DATA SHEET

## SECTION 1 - IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/ UNDERTAKING

### Contact information

#### General



Par Sterile Products  
870 Parkdale Road, Rochester, M.I. 48307  
T: +1 (800) 828-9393  
F: +1 (201) 829-9222  
E-mail: [drugsafety@parpharm.com](mailto:drugsafety@parpharm.com)

#### Emergency telephone number

Chemtrec (24-hour availability):  
+1 (800) 424-9300 (USA and Canada)  
+1 (703) 527-3887 (International; collect calls accepted)

<b>Product identifier</b>	Colistin Sulfate/Hydrocortisone/Neomycin/Thonzonium Bromide Otic
<b>Synonyms</b>	None identified
<b>Trade names</b>	Coly-Mycin® S Otic, Cortisporin® -TC Otic Suspension
<b>Chemical family</b>	Mixture - contains an antibiotic, a steroid, and a corticosteroid hormone.
<b>Relevant identified uses of the substance or mixture and uses advised against</b>	Bulk formulated pharmaceutical mixture/Formulated pharmaceutical product/mixture packaged in final form for patient use; used for the treatment of ear infections.
<b>Note</b>	This SDS is written to address potential worker health and safety issues associated with the handling of the formulated product/mixture. Workers manufacturing this product/mixture should consult the SDS of each hazardous ingredient for hazard information and handling recommendations.

## SECTION 2 - HAZARDS IDENTIFICATION

<b>Classification of the substance or mixture</b>	<b>Drugs in the finished state and intended for the final user are not subject to labeling in the US, EU or Canada.</b> Consult prescribing/packaging information. <b>The classification and labeling listed below is for bulk drug product.</b>
<b>Globally Harmonized System [GHS]</b>	Not classified

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**SECTION 2 - HAZARDS IDENTIFICATION ...continued**

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**Label elements**

<b>GHS hazard pictogram</b>	None required
<b>GHS signal word</b>	None required
<b>GHS hazard statements</b>	None required
<b>GHS precautionary statements</b>	None required

**Other hazards**

Coly-Mycin® S Otic contains the antibiotics colistin sulfate and neomycin, and the corticosteroid hydrocortisone acetate (hydrocortisone), which controls inflammation, edema, pruritus and other dermal reactions. Thonzonium bromide is a detergent that helps penetrate through cellular debris and secretions. As no data for the mixture were identified, applicable hazard information for individual ingredients is described below.

Adverse effects reported with clinical use of colistin sulfate include transient neurological disturbances (paresthesia, numbness, tingling, itchiness, vertigo/dizziness, slurred speech), nephrotoxicity, difficulty breathing, gastrointestinal discomfort (including potentially serious infections with *C. difficile*), rash, and fever. Neomycin may cause hearing damage with prolonged use, and has a potential for causing congenital deafness in humans if administered during pregnancy (a class effect). Sensitization reactions have also been reported with neomycin use. Corticosteroids (including hydrocortisone) suppress the inflammatory immune response, potentially delaying healing and increasing the risk of infection.

**Note**

This mixture does not meet criteria for classification under GHS as implemented by Regulation EC No 1272/2008 (EU CLP), WHMIS 2015 (Health Canada), and Hazard Communication Standard No. 1910.1200 (US OSHA). Nevertheless, it should be handled with caution as it contains pharmacologically active ingredients.

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**SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS**

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<u>Ingredient</u>	<u>CAS #</u>	<u>EINECS/ ELINCS#</u>	<u>Amount</u>	<u>GHS Classification</u>
Colistimethate Sodium	8068-28-8	232-516-9	<1%	STOT R1: H372; RT2: H361d
Neomycin sulfate	1405-10-3	215-766-3	<1%	RS1: H334; SS1: H317; STOT-R2: H373
Hydrocortisone	50-23-7	200-020-1	<5%	RT2: H361d

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## SECTION 3 - COMPOSITION/INFORMATION ON INGREDIENTS ...continued

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**Note** The substance(s) listed above are considered hazardous. The remaining components are not hazardous and/or present at amounts below reportable limits.

Amounts are listed as ranges; the exact percentage of composition is withheld as a trade secret. See Section 16 for full text of GHS classifications.

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## SECTION 4 - FIRST AID MEASURES

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### Description of first aid measures

<b>Immediate Medical Attention Needed</b>	No. If exposed or concerned: Get medical advice/attention.
<b>Eye Contact</b>	If easy to do, remove contact lenses, if worn. Immediately flush eyes with copious quantities of water for at least 15 minutes. If irritation occurs or persists, notify medical personnel and supervisor.
<b>Skin Contact</b>	Wash exposed area with soap and water and remove contaminated clothing/shoes. If irritation occurs or persists, notify medical personnel and supervisor.
<b>Inhalation</b>	Immediately move exposed subject to fresh air. If not breathing, give artificial respiration. If breathing is labored, administer oxygen. Immediately notify medical personnel and supervisor.
<b>Ingestion</b>	Do not induce vomiting unless directed by medical personnel. Do not give anything to drink unless directed by medical personnel. Never give anything by mouth to an unconscious person. Notify medical personnel and supervisor.
<b>Protection of first aid responders</b>	See Section 8 for Exposure Controls/Personal Protection recommendations.
<b>Most important symptoms and effects, both acute and delayed</b>	See Sections 2 and 11.
<b>Indication of immediate medical attention and special treatment needed, if necessary</b>	Medical conditions aggravated by exposure: None known or reported. Treat symptomatically and supportively. If accidental exposure occurs to an individual who is also taking one or more concomitant medications, consult the respective package or prescribing information for potential drug interactions.

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## SECTION 5 - FIREFIGHTING MEASURES

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<b>Extinguishing media</b>	Use water spray (fog), foam, dry powder, or carbon dioxide, as appropriate for surrounding fire and materials.
<b>Specific hazards arising from the substance or mixture</b>	No information identified. May emit carbon monoxide, carbon dioxide, oxides of nitrogen, and sulfur-containing compounds.

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**SECTION 5 - FIREFIGHTING MEASURES ...continued**

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<b>Flammability/ Explosivity</b>	No explosivity or flammability data identified. As product is an aqueous solution, it is not expected to be flammable or explosive.
<b>Advice for firefighters</b>	Wear full protective clothing and a self-contained breathing apparatus with a full facepiece operated in the pressure demand or other positive pressure mode. Decontaminate all equipment after use.

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**SECTION 6 - ACCIDENTAL RELEASE MEASURES**

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<b>Personal precautions, protective equipment and emergency procedures</b>	If vials are opened, crushed or broken, take proper precautions to minimize exposure by using appropriate personal protective equipment (see Section 8). Area should be adequately ventilated. Do not breathe dust/mist/vapors/spray.
<b>Environmental precautions</b>	Do not empty into drains. Avoid release to the environment.
<b>Methods and material for containment and cleaning up</b>	If vials are crushed or broken, DO NOT CAUSE MATERIAL TO BECOME AIRBORNE. For small spills, soak up material with absorbent, e.g., paper towels. For large spills, cordon off spill area and minimize the spreading of spilled material. Soak up material with absorbent. Collect spilled material, absorbent, and rinse water into suitable containers for proper disposal in accordance with applicable waste disposal regulations (see Section 13). Decontaminate the area twice.
<b>Reference to other sections</b>	See Sections 8 and 13 for more information.

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**SECTION 7 - HANDLING AND STORAGE**

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<b>Precautions for safe handling</b>	If vials are opened, crushed or broken, drug substance may be released. Minimize dust generation and accumulation. Follow recommendations for handling cytotoxic antineoplastic agents (i.e., use of engineering controls and/or other personal protective equipment if needed). Wash thoroughly after handling. Avoid breathing dust.
<b>Conditions for safe storage including any incompatibilities</b>	Store at 20-25°C (68-77°F) and protect from light.
<b>Specific end use(s)</b>	Pharmaceutical.

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**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION**

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<b>Note</b>	Wash hands, face and other potentially exposed areas immediately in the event of physical contact. Dispose of broken vials in a sharps container.
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**SECTION 8 - EXPOSURE CONTROLS/PERSONAL PROTECTION ...continued**

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**Control Parameters/  
Occupational Exposure  
Limit Values**

<u>Compound</u>	<u>Issuer</u>	<u>Type</u>	<u>OEL</u>
Colistimethate Sodium	--	--	--
Neomycin sulfate	--	--	--
Hydrocortisone	--	--	--

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**Exposure/Engineering  
controls**

None required for normal handling of packaged product. If handling bulk product and/or vials are open/crushed/broken: Selection and use of containment devices and personal protective equipment should be based on a risk assessment of exposure potential. Use local exhaust and/or enclosure at aerosol/mist-generating points. Emphasis is to be placed on closed material transfer systems and process containment, with limited open handling. High-energy operations should be done within an approved emission control or containment system.

**Respiratory  
protection**

None required for normal handling of packaged product. If handling bulk product and/or vials are open/crushed/broken: Choice of respiratory protection should be appropriate to the task and the level of existing engineering controls. Respirators are generally not required. At minimum, a tight-fitting full-face respirator with HEPA filters is required for spill cleanup.

**Hand protection**

None required for the normal handling of packaged product. Wear nitrile or other impervious gloves if skin contact with tablets is possible.

**Skin protection**

Wear appropriate gloves, lab coat, or other protective overgarment if skin contact is likely. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use.

**Eye/face protection**

None required for normal handling of packaged product. Wear safety glasses with side shields if eye contact is likely, e.g., during clean up of large spill. Base the choice of protection on the job activity and potential for contact with eyes and face.

**Environmental  
Exposure Controls**

Avoid release to the environment and operate within closed systems wherever practicable. Air and liquid emissions should be directed to appropriate pollution control devices. In case of spill, do not release to drains. Implement appropriate and effective emergency response procedures to prevent release or spread of contamination and to prevent inadvertent contact by personnel.

**Other protective  
measures**

Wash hands in the event of contact with tablets, especially before eating, drinking or smoking. Protective equipment is not to be worn outside the work area (e.g., in common areas or out-of-doors).

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**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES**

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**Information on basic  
physical and chemical  
properties****Appearance**

Aqueous suspension of white to off-white solids which settle rapidly.

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**SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES ...continued**

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<b>Color</b>	Cloudy white.
<b>Odor</b>	Odorless
<b>Odor threshold</b>	No information identified.
<b>pH</b>	5.0
<b>Melting point/ freezing point</b>	No information identified.
<b>Initial boiling point and boiling range</b>	No information identified.
<b>Flash point</b>	No information identified.
<b>Evaporation rate</b>	No information identified.
<b>Flammability (solid, gas)</b>	Not applicable.
<b>Upper/lower flammability or explosive limits</b>	Not applicable.
<b>Vapor pressure</b>	No information identified
<b>Vapor density</b>	No information identified.
<b>Relative density</b>	No information identified.
<b>Water solubility</b>	Soluble.
<b>Solvent solubility</b>	No information identified.
<b>Partition coefficient (<i>n</i>-octanol/water)</b>	No information identified.
<b>Auto-ignition temperature</b>	No information identified.
<b>Decomposition temperature</b>	No information identified.
<b>Viscosity</b>	No information identified.
<b>Explosive properties</b>	No information identified.
<b>Oxidizing properties</b>	No information identified.
<b>Other information</b>	
<b>Molecular formula</b>	Not applicable (Mixture)
<b>Molecular weight</b>	Not applicable (Mixture)

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**SECTION 10 - STABILITY AND REACTIVITY**

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<b>Reactivity</b>	No information identified.
<b>Chemical stability</b>	No information identified.
<b>Possibility of hazardous reactions</b>	No information identified.
<b>Conditions to avoid</b>	Avoid extreme temperatures.
<b>Incompatible materials</b>	No information identified.
<b>Hazardous decomposition products</b>	See Section 5 - Hazardous combustion products.

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**SECTION 11 - TOXICOLOGICAL INFORMATION**

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**Note** No data on product formulation. The following information is for the active ingredients, where applicable.

**Information on toxicological effects**

**Route of entry** May be absorbed by inhalation, skin contact and ingestion.

**Acute toxicity**

<u>Compound</u>	<u>Type</u>	<u>Route</u>	<u>Species</u>	<u>Dose</u>
Colistimethate Sodium	LD <sub>50</sub>	Oral	Rat	5450 mg/kg
Neomycin sulfate	LD <sub>50</sub>	Oral	Rat	2750 mg/kg
	LD <sub>50</sub>	Oral	Mouse	2880 mg/kg
Hydrocortisone	LD <sub>50</sub>	Oral	Rat/Mouse	>5000 mg/kg

**Irritation/Corrosion** Neomycin and hydrocortisone are mild skin irritants.

**Sensitization** Neomycin is a skin sensitizer.

**STOT-single exposure** No studies identified.

**STOT-repeated exposure/Repeat-dose toxicity** Colistimethate sodium: An IM dose of 60 mg/kg/day for 30 days and IP dose of  $\geq 10$  mg/kg/day for 6-months in rats resulted in convulsions and lethality. Target organs of toxicity included kidneys, liver, and spleen.  
Neomycin: Oral doses up to 12.5 mg/kg/day for 84-weeks in rats were well tolerated. Some animals showed hearing loss by the end of the study though the effect was not significant.

**Reproductive toxicity** Colistimethane sodium: No adverse effects on fertility were observed in male and female rats given IM doses up to 9.3 mg/kg/day.  
Neomycin: Fertility studies have not been performed with neomycin, but reports from the scientific literature suggest that it may decrease spermatogenesis in rats.

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**SECTION 11 - TOXICOLOGICAL INFORMATION** ...continued

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<b>Developmental toxicity</b>	Colistimethate sodium: In rabbits and rats, IM doses up to 9.3 mg/kg/day were not teratogenic. Increased resorptions in rabbits and decreased pup survival were observed at the highest dose. Hydrocortisone: Corticosteroids are generally teratogenic in laboratory animals when administered systemically at relatively low doses. Neomycin: Aminoglycosides (as a drug class) can cause congenital deafness in the developing fetus at high systemic exposures.
<b>Genotoxicity</b>	Colistimethate sodium and neomycin: An increased incidence of chromosome aberrations in <i>in vitro</i> assay in human lymphocytes has been reported. Hydrocortisone: Mutagenicity studies were negative.
<b>Carcinogenicity</b>	Hydrocortisone: Long term studies in rodents showed no evidence of carcinogenicity attributable to oral administration of corticosteroids. None of the components of this mixture present at levels greater than or equal to 0.1% are listed by NTP, IARC, ACGIH or OSHA as a carcinogen.
<b>Aspiration hazard</b>	No data available.
<b>Human health data</b>	See "Section 2 - Other Hazards"

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**SECTION 12 - ECOLOGICAL INFORMATION**

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**Toxicity**

<u>Compound</u>	<u>Type</u>	<u>Species</u>	<u>Concentration</u>
Colistimethate Sodium	--	--	--
Neomycin sulfate	--	--	--
Hydrocortisone	--	--	--

<b>Persistence and Degradability</b>	No data available.
<b>Bioaccumulative potential</b>	No data available.
<b>Mobility in soil</b>	No data available.
<b>Results of PBT and vPvB assessment</b>	Not performed.
<b>Other adverse effects</b>	No data available.
<b>Note</b>	The ecological characteristics of this mixture have not been fully investigated. Releases to the environment should be avoided.



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**SECTION 13 - DISPOSAL CONSIDERATIONS**

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**Waste treatment methods** Dispose of wastes in accordance to prescribed federal, state, and local guidelines, e.g., appropriately permitted chemical waste incinerator. Do not send down the drain or flush down the toilet. All wastes containing the material should be properly labeled. Rinse waters resulting from spill cleanups should be discharged in an environmentally safe manner, e.g., appropriately permitted municipal or on-site wastewater treatment facility.

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**SECTION 14 - TRANSPORT INFORMATION**

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**Transport** Based on the available data, this product/mixture is not regulated as a hazardous material/dangerous good under EU ADR/RID, US DOT, Canada TDG, IATA, or IMDG.

**UN number** None assigned.

**UN proper shipping name** None assigned.

**Transport hazard classes and packing group** None assigned.

**Environmental hazards** This product/mixture is not regulated as an environmental hazard or a marine pollutant.

**Special precautions for users** Avoid release to the environment.

**Transport in bulk according to Annex II of MARPOL73/78 and the IBC Code** Not applicable.

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**SECTION 15 - REGULATORY INFORMATION**

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**Safety, health and environmental regulations/legislation specific for the substance or mixture** This SDS generally complies with the requirements listed under current guidelines in the US, EU and Canada. Consult your local or regional authorities for more information.

**Chemical safety assessment** Not conducted.

**TSCA status** Drugs are exempt from TSCA.

**SARA section 313** Not listed.

**California proposition 65** Not listed.

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**SECTION 15 - REGULATORY INFORMATION** ...continued

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**Additional information** No other information identified.

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**SECTION 16 - OTHER INFORMATION**

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**Full text of H phrases and GHS classifications** H372 - Causes damage to liver, kidneys, and spleen through prolonged or repeated exposure. STOT-R1 - Specific Target Organ Toxicity Following Repeat Exposure Category 1. H361d - Suspected of damaging the unborn child. RT2 - Reproductive toxicity Category 2. H334 - May cause allergic or asthmatic symptoms or breathing difficulty if inhaled. RS1 - Respiratory Sensitizer Category 1. H317 - May cause an allergic skin reaction. SS1 - Skin sensitizer Category 1. H373 - May cause damage to hearing through prolonged or repeated exposure. STOT-R2 - Specific Target Organ Toxicity Following Repeated Exposure Category 2.

**Sources of data** Information from published literature and internal company data.

**Abbreviations** ACGIH - American Conference of Governmental Industrial Hygienists; ADR/RID - European Agreement Concerning the International Carriage of Dangerous Goods by Road/Rail; AIHA - American Industrial Hygiene Association; CAS# - Chemical Abstract Services Number; CLP - Classification, Labelling, and Packaging of Substances and Mixtures; DNEL - Derived No Effect Level; DOT - Department of Transportation; EINECS - European Inventory of New and Existing Chemical Substances; ELINCS - European List of Notified Chemical Substances; EU - European Union; GHS - Globally Harmonized System of Classification and Labeling of Chemicals; IARC - International Agency for Research on Cancer; IDLH - Immediately Dangerous to Life or Health; IATA - International Air Transport Association; IMDG - International Maritime Dangerous Goods; LOEL - Lowest Observed Effect Level; LOAEL - Lowest Observed Adverse Effect Level; NIOSH - The National Institute for Occupational Safety and Health; NOEL - No Observed Effect Level; NOAEL - No Observed Adverse Effect Level; NTP - National Toxicology Program; OEL - Occupational Exposure Limit; OSHA - Occupational Safety and Health Administration; PBT - Persistent, Bioaccumulative, and Toxic; PNEC - Predicted No Effect Concentration; SARA - Superfund Amendments and Reauthorization Act; STOT - Specific Target Organ Toxicity; STEL - Short Term Exposure Limit; TDG - Transportation of Dangerous Goods; TSCA - Toxic Substances Control Act; TWA - Time Weighted Average; vPvB - Very Persistent and Very Bioaccumulative; WHMIS - Workplace Hazardous Materials Information System

**Issue Date** 24 May 2019

**Revisions** Updated general format for compliance with most recent regulatory requirements in the US, EU, and Canada.

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**SECTION 16 - OTHER INFORMATION ...continued**

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**Disclaimer**

The above information is based on data available to us and is believed to be correct. Since the information may be applied under conditions beyond our control and with which we may be unfamiliar, we do not assume any responsibility for the results of its use and all persons receiving it must make their own determination of the effects, properties and protections which pertain to their particular conditions.

No representation, warranty, or guarantee, express or implied (including a warranty of fitness or merchantability for a particular purpose), is made with respect to the materials, the accuracy of this information, the results to be obtained from the use thereof, or the hazards connected with the use of the material. Caution should be used in the handling and use of the material because it is a pharmaceutical product. The above information is offered in good faith and with the belief that it is accurate. As of the date of issuance, we are providing all information relevant to the foreseeable handling of the material. However, in the event of an adverse incident associated with this product, this Safety Data Sheet is not, and is not intended to be, a substitute for consultation with appropriately trained personnel.