

**SAFETY DATA SHEET****1. Identification**

**Product Identifier:** Vancomycin Hydrochloride Capsules, USP

**Synonyms:** Vancomycin, monohydrochloride

**National Drug Code (NDC):** 17478-741-02  
17478-742-02

**Recommended Use:** Pharmaceutical.

**Company:** Akorn, Inc.  
1925 West Field Court, Suite 300  
Lake Forest, Illinois 60045

**Contact Telephone:** 1-800-932-5676

**E mail:** customer.service@akorn.com

**Emergency Phone Number:** CHEMTREC 1-800-424-9300 (U.S. and Canada)

**2. Hazard(s) Identification**

**Physical Hazards:** Not classifiable.

**Health Hazards:** Not classifiable.

**Symbol(s):** None.

**Signal Word:** None.

**Hazard Statement(s):** None.

**Precautionary Statement(s):** None.

**Hazards Not Otherwise Classified:** Not classifiable.

**Supplementary Information:** While this material is not classifiable as hazardous under the OSHA standard, this SDS contains valuable information critical to safe handling and proper use of the product. This SDS should be retained and available for employees and other users of this product.

**3. Composition/Information on Ingredients**

Chemical Name	CAS Number	Synonyms	Chemical Formula	Molecular Weight	Percentage
Vancomycin Hydrochloride	1404-93-9	Vancomycin, monohydrochloride	$C_{66}H_{75}Cl_2N_9O_{24} \cdot HCl$	1485.71	12.5% and 25 %

The 125 mg capsules contain Vancomycin Hydrochloride equivalent to 125 mg (0.08 mmol) Vancomycin. These capsules also contain FD&C Blue No. 2, Gelatin, Iron Oxide Yellow and Red, Polyethylene Glycol 6000, and Titanium Dioxide.

The 250 mg capsules contain Vancomycin Hydrochloride equivalent to 250 mg (0.17 mmol) Vancomycin. These capsules also contain FD&C Blue No. 2, Gelatin, Iron Oxide Red and Black, Polyethylene Glycol 6000, and Titanium Dioxide.

Both 125 mg and 250 mg capsules are imprinted with white ink which may contain purified Shellac, purified Titanium Dioxide and FD&C Blue No. 1 Lake.

**4. First Aid Measures**

<b>Ingestion:</b>	If a person vomits place them in the recovery position so that vomit will not reenter the mouth and throat. Rinse mouth with water. If swallowed, seek medical advice immediately and show the container or label. Treat symptomatically and supportively. Ensure that medical personnel are aware of the material(s) involved and take precautions to protect themselves.
<b>Eye Contact:</b>	Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Skin Contact:</b>	Remove from source of exposure. Remove and isolate contaminated clothing and shoes. Flush with copious amounts of water for at least 20 minutes. Use soap. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Inhalation:</b>	Remove from source of exposure. Move individual(s) to fresh air. Give artificial respiration if individual(s) are not breathing and call emergency medical service. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary. Ensure that medical personnel are aware of the material(s) involved and are aware of precautions to protect themselves.
<b>Protection of First-Aiders:</b>	Use personal protective equipment (see section 8).
<b>Signs and Symptoms:</b>	Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Side effects from therapeutic doses may include: Nephrotoxicity, ototoxicity, reversible neutropenia, thrombocytopenia, drug fever, nausea, chills, Stevens-Johnson syndrome, and toxic epidermal necrolysis. Occupational exposure has not been fully investigated.
<b>Medical Conditions Aggravated by Exposure:</b>	Not determined.
<b>Notes to Physician:</b>	Treat supportively and symptomatically.

**5. Firefighting Measures**

**Suitable Extinguishing Media:** Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

**Unsuitable Extinguishing Media:** Not determined.

**Specific Hazards Arising from the Chemical:**

**Hazardous Combustion Products:** Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

**Other Specific Hazards:** Not determined.

**Special Protective Equipment/  
Precautions for Firefighters:** Wear self-contained breathing apparatus and full and protective gear.

**6. Accidental Release Measures**

**Personal Precautions:** Use personal protective equipment recommended in Section 8 of this document and isolate the hazard area.

**Personal Protective Equipment:** For personal protection see section 8.

**Methods for Cleaning Up:** This material will settle out of the air. Use an industrial vacuum cleaner with a high efficiency filter to clean up dust. Avoid dust generation.

**Environmental Precautions:** Avoid runoff into storm sewers, ditches, and waterways.

**Reference to Other Sections:** Refer to Sections 8, 12 and 13 for further information.

**7. Handling and Storage**

**Precautions for Safe Handling:** When handling pharmaceutical products, avoid all contact and inhalation of dust, particulates and/or powder. Use with adequate ventilation. Handle in accordance with product label and/or product insert information. Handle in accordance with good industrial hygiene and safety practices.

**Conditions for Safe Storage,  
Including Any Incompatibilities:** Store at 15°C – 25°C (59°F – 77°F). Store according to label and/or product insert information.

**Specific End Use:** Pharmaceuticals.

**8. Exposure Controls/Personal Protection****Occupational Exposure Guidelines:**

<b>Common or Chemical Name</b>	<b>Employee Exposure Limits</b>
Vancomycin Hydrochloride	Not established.
Titanium Dioxide	OSHA: 15 mg/m <sup>3</sup> , TWA ACGIH TLV: 10 mg/m <sup>3</sup>

**Engineering Controls:**

General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended oral administration purpose in a controlled medical setting. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits.

**Respiratory Protection:**

No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. Where respirators are deemed necessary to reduce or control occupational exposures, use NIOSH-approved respiratory protection and have an effective respirator program in place (applicable U.S. regulation OSHA 29 CFR 1910.134).

**Eyes Protection:**

Safety glasses with side shields are recommended. Face shields or goggles may be required if splash potential exists or if corrosive materials are present. Approved eye protection (e.g., bearing the ANSI Z87 or CSA stamp) is preferred. Maintain eyewash facilities in the work area.

**Hand Protection:**

Wear chemically compatible gloves. For handling solutions, ensure that the glove material is protective against the solvent being used. Use handling practices that minimize direct hand contact. Employees who are sensitive to natural rubber (latex) should use nitrile or other synthetic non-latex gloves. Use of powdered latex gloves should be avoided due to the risk of latex allergy.

**Skin Protection:**

Wear protective laboratory coat, apron, or disposable garment when working with large quantities.

**9. Physical and Chemical Properties**

<b>Physical State/Color:</b>	Opaque blue, opaque brown capsule.
<b>Odor:</b>	No data available.
<b>Odor Threshold:</b>	No data available.
<b>pH:</b>	No data available.
<b>Melting Point:</b>	No data available.
<b>Freezing Point:</b>	No data available.
<b>Boiling Point:</b>	No data available.
<b>Flash Point:</b>	No data available.
<b>Evaporation Rate:</b>	No data available.
<b>Flammability (solid, gas):</b>	No data available.
<b>Flammability Limit - Lower:</b>	No data available.
<b>Flammability Limit - Upper:</b>	No data available.
<b>Vapor Pressure:</b>	No data available.
<b>Vapor Density:</b>	No data available.
<b>Relative Density:</b>	No data available.
<b>Solubility(ies):</b>	Soluble in water.
<b>Partition Coefficient (n-octanol/water):</b>	No data available.
<b>Auto-Ignition Temperature:</b>	No data available.
<b>Decomposition Temperature:</b>	No data available.
<b>Viscosity:</b>	No data available.

**10. Stability and Reactivity**

<b>Reactivity:</b>	No data available.
<b>Chemical Stability:</b>	Stable under recommended storage conditions.
<b>Possibility of Hazardous Reactions:</b>	No data available.
<b>Conditions to Avoid (e.g., static discharge, shock, or vibration):</b>	No conditions contributing to instability are known to exist for normal handling of this product.
<b>Incompatible Materials:</b>	No data available.
<b>Hazardous Decomposition Products:</b>	No data available.
<b>Hazardous Polymerization:</b>	Not reported.

**11. Toxicological Information****Information on the Likely Routes of Exposure:**

<b>Inhalation:</b>	Inhalation of dusts from this product may irritate the nose, throat, lungs and upper respiratory tract.
<b>Ingestion:</b>	Ingestion of large amounts is harmful.
<b>Skin Contact:</b>	Skin contact with dust, particulates, and/or powder from this product may cause irritation.

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**Eye Contact:** Eye contact with dusts, powder or process fumes may cause irritation of the eyes.

**Symptoms Related to the Physical, Chemical and Toxicological Characteristics:**

See Section 4. To the best of our knowledge, the chemical, physical and toxicological properties have not been thoroughly investigated.

**Delayed and Immediate Effects of Exposure:**

No data available.

**Acute Toxicity:**

Compound	Species	Route	End Point	Dose
Vancomycin Hydrochloride	Rat	Oral	LD <sub>50</sub>	>10 mg/kg
Vancomycin Hydrochloride	Mouse	Intravenous	LD <sub>50</sub>	489 mg/kg
Vancomycin Hydrochloride	Rat	Intravenous	LD <sub>50</sub>	319 mg/kg
Vancomycin Hydrochloride	Mouse	Intraperitoneal	LD <sub>50</sub>	1,734 mg/kg
Vancomycin Hydrochloride	Rat	Intraperitoneal	LD <sub>50</sub>	2,218 mg/kg
Vancomycin Hydrochloride	Mouse	Subcutaneous	LD <sub>50</sub>	5 mg/kg
Polyethylene Glycol 6000	Rat	Oral	LD <sub>50</sub>	28 mg/kg
Polyethylene Glycol 6000	Rat	Oral	LD <sub>50</sub>	31,640 mg/kg
Polyethylene Glycol 6000	Rat	Oral	LD <sub>50</sub>	27,500 mg/kg
Polyethylene Glycol 6000	Rat	Oral	LD <sub>50</sub>	30,200 mg/kg
Polyethylene Glycol 6000	Rat	Oral	LD <sub>50</sub>	600 mg/kg
Polyethylene Glycol 6000	Rat	Oral	LD <sub>50</sub>	30 mg/kg
Polyethylene Glycol 6000	Rat	Oral	LD <sub>50</sub>	32 mg/kg
Polyethylene Glycol 6000	Rat	Oral	LD <sub>50</sub>	1,054 mg/kg
Polyethylene Glycol 6000	Rat	Oral	LD <sub>50</sub>	51,310 mg/kg

**Irritation/Sensitization:**

Compound	Species	Study Type	Dose	Severity
Polyethylene Glycol 6000	Rabbit	Eye irritation	500 mg/24H	Mild
Polyethylene Glycol 6000	Rabbit	Eye irritation	100 uL	Mild
Polyethylene Glycol 6000	Rabbit	Eye irritation	500 mg	Mild
Polyethylene Glycol 6000	Rabbit	Skin irritation	>20 mL/kg	Not reported
Polyethylene Glycol 6000	Rabbit	Skin irritation	>20 mg/kg	Not reported
Titanium Dioxide	Human	Skin irritation	300 ug/3D	Intermittent
Titanium Dioxide	Rat	TD <sub>LO</sub> - Ingestion	60 gm/kg	Gastrointestinal – Hypermotility, diarrhea

**Acute Toxicity – Dermal:** No data available.  
**Acute Toxicity – Inhalation:** No data available.  
**Corrosivity:** No data available.  
**Dermal Irritation:** No data available.  
**Eye Irritation:** No data available.  
**Sensitization:** No data available.  
**Toxicokinetics/Metabolism:** No data available.  
**Target Organ Effects:** No data available.  
**Reproductive Effects:** No data available.  
**Carcinogenicity:** No data available.

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National Toxicology Program (NTP): Not considered to be a carcinogen.

International Agency for Research on Cancer (IARC): Not considered to be a carcinogen.

Occupational Safety and Health Administration (OSHA): Not considered to be a carcinogen.

**Mutagenicity:** No data available.

**Aspiration Hazard:** No data available.

### 12. Ecological Information

#### Ecotoxicity

**Aquatic:** No data available.

**Terrestrial:** No data available.

**Persistence and Degradability:** No data available.

**Bioaccumulative Potential:** No data available.

**Mobility in Soil:** No data available.

**Mobility in Environment:** No data available.

**Other Adverse Effects:** No data available.

### 13. Disposal Considerations

Dispose of all waste in accordance with Federal, State and Local regulations.

### 14. Transport Information

**UN Number:** Not applicable.

**UN Proper Shipping Name:** Not applicable.

**Transport Hazard Class(es):** Not applicable.

**Packing Group:** Not applicable.

**Department of Transportation:** Not regulated as a hazardous material.

**International Air Transport Association (IATA):** Not regulated as a dangerous good.

**International Maritime Dangerous Good (IMDG):** Not regulated as a dangerous good.

### 15. Regulatory Information

#### US Federal Regulations:

**Toxic Substance Control Act (TSCA):** Polyethylene Glycol 6000: Listed.  
Gelatin: Listed  
Titanium Dioxide: Listed.

**CERCLA Hazardous Substance and Reportable Quantity:** Not listed.

**SARA 313:** Not listed.

**SARA 302:** Not listed.

**State Regulations**

<b>Massachusetts:</b>	Not listed.
<b>New Jersey:</b>	Not listed.
<b>Pennsylvania:</b>	Not listed.
<b>California Proposition 65:</b>	Not listed.

**16. Other Information****HMIS Classification:**

Health Hazard:	2
Fire Hazard:	1
Reactivity:	1

**Revision Date:** 05/18/2015**Revision Number:** 0

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