



## **SAFETY DATA SHEET**

<b>Section 1: Identification</b>	
<b>Material</b>	Vancomycin hydrochloride for injection USP 500 mg/vial and 1 g/vial
<b>Recommended use</b>	Used to treat fungal infections
<b>Manufacturer</b>	Aspiro Pharma Limited, Sy. No. 321, Biotech Park, Phase-III, Karkapatla Village, Markook Mandal, Telangana (S), Siddipet (Dist.)-502281, India.
<b>Distributor</b>	Camber Pharmaceuticals, Inc., Piscataway, NJ 08854
<b>Section 2: Hazard(s) Identification</b>	
<b>Hazard Statement</b>	Non-hazardous in accordance with international standards for workplace safety.
<b>Additional Hazard Information: Short Term:</b>	Accidental ingestion may cause effects similar to those seen in clinical use.
<b>Known Clinical Effects:</b>	Adverse effects associated with therapeutic use include effects on hearing, kidney effects, blood cell changes, fever, chills, allergic skin rash. Ingestion of this material may cause effects similar to those generally seen in clinical use of antibiotics including gastrointestinal irritation, vomiting, transient diarrhea, nausea, and abdominal pain. reuse.
<b>EU Indication of danger:</b>	Not classified
<b>Section 3: Composition/Information on Ingredients</b>	
<b>Chemical Name</b>	Vancomycin hydrochloride
<b>CAS</b>	1404-93-9
<b>Section 4: First-Aid Measures</b>	
<b>Inhalation</b>	Remove to fresh air and keep patient at rest. Seek medical attention immediately.
<b>Skin contact</b>	Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.
<b>Eye contact</b>	Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.



<b>Ingestion</b>	Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.
<b>Section 5: Fire-Fighting Measures</b>	
<b>Suitable extinguishing media</b>	Use carbon dioxide, dry chemical, or water spray.
<b>Hazardous combustion products</b>	Emits toxic fumes of carbon monoxide, carbon dioxide, and nitrogen oxides.
<b>Fire / Explosion Hazards:</b>	Fine particles (such as dust and mists) may fuel fires/ explosions.
<b>Fire Fighting Procedures:</b>	During all fire-fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.
<b>Section 6: Accidental Release Measures</b>	
Health and Safety Precautions:	Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure.
Measures for Environmental Protections:	Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.
Measures for Cleaning / Collecting:	Contain the source of spill if it is safe to do so. Collect spilled material by a method that controls dust generation. A damp cloth or a filtered vacuum should be used to clean spills of dry solids. Clean spill area thoroughly.
<b>Section 7: Handling and Storage</b>	
General Handling:	Minimize dust generation and accumulation. Avoid breathing dust. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment. Wash hands and any exposed skin after removal of PPE. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste-water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.
Storage Conditions:	Store as directed by product packaging.
<b>8. Exposure controls / personal protection</b>	
Vancomycin hydrochloride	OEL TWA-8 Hr: 100µg/m <sup>3</sup>
Personal protective equipment	



<b>Respiratory protection</b>	If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.
<b>Hand protection</b>	Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.
<b>Eye protection</b>	Wear safety glasses or goggles if eye contact is possible.
<b>Skin and body protection</b>	Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations
<b>Section 9: Physical and Chemical Properties</b>	
<b>Physical State</b>	Powder
<b>Description</b>	<p>Vancomycin Hydrochloride for Injection, USP, is a white to tan lyophilized cake or powder, for preparing intravenous infusions, in vials each containing the equivalent of 500 mg or 1 g vancomycin base. 500 mg of the base is equivalent to 0.34 mmol. When reconstituted with Sterile Water for Injection to a concentration of 50 mg/mL, the pH of the solution is between 2.5 and 4.5. This product is oxygen sensitive. Vancomycin Hydrochloride for Injection, USP should be administered intravenously in diluted solution.</p> <p><b>500 mg/ Vial</b>  10 vials per carton                      31722-210-10  25 vials per carton                      31722-210-32</p> <p><b>1 gram/ Vial</b>  10 vials per carton                      31722-211-10</p>
<b>Section 10: Stability and Reactivity</b>	
<b>Chemical stability</b>	Stable under normal conditions of use.
<b>Conditions to avoid</b>	Fine particles (such as dust and mists) may fuel fires/explosions.
<b>Incompatible materials</b>	As a precautionary measure, keep away from strong oxidizers



### Section 11: Toxicological Information

#### Acute toxicity

#### Vancomycin hydrochloride

Rat Oral LD50 > 10 g/kg  
Rat Para-periosteal LD50 319 mg/kg

#### Reproduction & Development Toxicity:

Embryo / Fetal Development Rat Intravenous 200 mg/kg/day NOAEL Not teratogenic  
Embryo / Fetal Development Rabbit Intravenous 120 mg/kg/day NOAEL Not Teratogenic

### Section 12: Ecological Information

**Environmental Overview:** Environmental properties have not been investigated.

#### Persistence and degradability

No data available

#### Bioaccumulative potential

No data available

#### Mobility in soil

No data available

#### Other adverse effects

No data available

### Section 13: Disposal Considerations

#### Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

### Section 14: Transport Information

**The following refers to all modes of transportation unless specified below.  
Not regulated for transport under USDOT, EUADR, IATA, or IMDG regulations.**



### Section 15: Regulatory Information

**EU Indication of danger:** Not classified

**OSHA Label:**

**Non-hazardous in accordance with international standards for workplace safety.**

### Section 16: Other Information, including date of preparation or last revision

**Issue Date:** 30-11-2022

**Version:** 00

**Further information**

**Revision date:** NA

**Revision note:** NA

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