SAFETY DATA SHEET

Product Name: **Vancomycin Hydrochloride for Injection, USP**

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
Emergency Telephone #'s	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
Hospira, Inc., Non-Emergency	224 212-2000
Product Name	Vancomycin Hydrochloride for Injection, USP
Synonyms	Vancomycin Hydrochloride

2. HAZARD(S) IDENTIFICATION

Emergency Overview

Vancomycin Hydrochloride for Injection, USP is a powder containing vancomycin hydrochloride, a purified tricyclic glycopeptide antibiotic derived from *Amycolatopsis orientalis* (formerly *Nocardia orientalis*). Clinically, it is used to treat potentially, life-threatening infections. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract, and a potential contact sensitizer which may induce allergic skin reactions. Based on clinical use, possible target organs include the auditory system, the hematopoietic system, and the kidneys.

U.S. OSHA GHS Classification

Physical Hazards	**Hazard Class**	**Hazard Category**
	Not Classified	Not Classified

Health Hazards	**Hazard Class**	**Hazard Category**
	Eye Damage / Irritation	2B
	Sensitization – Skin	1
	STOT - RE	2

Label Element(s)

Pictogram

Signal Word Danger

Hazard Statement(s)

Causes eye irritation
May cause an allergic skin reaction
May cause damage to organ through prolonged or repeated exposure

2. HAZARD(S) IDENTIFICATION: continued

Precautionary Statement(s)

Prevention

Do not breathe vapor or spray
Contaminated work clothing must not be allowed out of the workplace
Wear protective gloves
Wash hands thoroughly after handling

Response

Get medical attention if you feel unwell.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Vancomycin Hydrochloride
Chemical Formula $C_{66}H_{75}Cl_2N_9O_{24}$• HCl

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Vancomycin Hydrochloride	100	1404-93-9	YW4380000

May contain hydrochloric acid and/or sodium hydroxide for pH adjustment.

4. FIRST AID MEASURES

Eye Contact

Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Contact

Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion

Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability

None anticipated for this product. However, many organic powders will combust at elevated temperatures.

Fire & Explosion Hazard

None anticipated for this product. Avoid the generation of dusty environments.

Extinguishing Media

As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.

Special Fire Fighting Procedures

No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal

For spilled powder, isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. Collect the spilled powder using techniques that minimize powder migration. Clean affected area with soap and water. Absorb any liquid with an inert absorbent material (e.g. absorbent pad). Dispose of materials according to the applicable federal, state, or local regulations.

If a spill occurs after reconstitution, absorb liquid with suitable material and clean affected area with soap and water. Dispose of materials according to the applicable federal, state, or local regulations.

7. HANDLING AND STORAGE

Handling

No special handling required for hazard control under conditions of normal product use.

Storage

No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions

No special precautions are required for hazard control. Employees with known allergies to vancomycin hydrochloride or related antibiotics should consult a health and/or safety professional prior to handling open containers of this material.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure Limits			
Component	**OSHA-PEL**	**ACGIH-TLV**	**AIHA WEEL**	**Hospira EEL**
Vancomycin Hydrochloride	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: Not Established	8 hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
AIHA WEEL: Workplace Environmental Exposure Level
EEL: Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.

Respiratory Protection

Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne dust or aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin Protection

If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye Protection

Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls

Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Off-white to white to tan lyophilized powder
Odor	NA
Odor Threshold	NA
pH	When reconstituted, forms a clear solution in water with a pH of 4.0 (2.5 to 4.5)
Melting point/Freezing Point	NA
Initial Boiling Point/Boiling Point Range	NA
Flash Point	NA
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	NA
Solubility	Freely soluble in water; slightly soluble in alcohol.
Partition Coefficient: n-octanol/water	NA
Auto-ignition Temperature	NA
Decomposition Temperature	NA
Viscosity	NA

10. STABILITY AND REACTIVITY

Reactivity	Not determined
Chemical Stability	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined
Conditions to Avoid	Not determined
Incompatibilities	Not determined
Hazardous Decomposition Products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), or hydrogen chloride.
Hazardous Polymerization	Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity - Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
*Vancomycin Hydrochloride	100	LD50	Oral	>5000	mg/kg	Rat
*Vancomycin Hydrochloride	100	LD50	Dermal	>500	mg/kg	Rabbit
*Vancomycin Hydrochloride	100	LD50	Intravenous	251-312 292	mg/kg mg/kg	Rat Dog
*Vancomycin Hydrochloride	100	LC50(1h)	Inhalation	3080	mg/m3	Rat
Vancomycin	100	LD50	Intravenous	319 430,489	mg/kg mg/kg	Rat Mouse
Vancomycin	100	LD50	Intraperitoneal	2218 1734 737	mg/kg mg/kg mg/kg	Rat Mouse Guinea Pig

LD50: Dosage that produces 50% mortality.
*Lilly MSDS

11. TOXICOLOGICAL INFORMATION: continued

Occupational Exposure Potential	Information on the absorption of this product via inhalation or skin contact is not available. Avoid dust or liquid aerosol generation and skin contact.
Signs and Symptoms	None anticipated from normal handling of this product. In clinical use, vancomycin hydrochloride has produced ototoxicity (deafness), renal injury, a drop in blood pressure (following intravenous administration), lowered leukocyte or eosinophil counts in the blood, and allergic reactions such as urticaria, rashes, nausea, chills, fever and even anaphylactic responses.
Aspiration Hazard	None anticipated from normal handling of this product.
Dermal Irritation/ Corrosion	None anticipated from normal handling of this product.
Ocular Irritation/ Corrosion	None anticipated from normal handling of this product. However, inadvertent contact of this product formulation with eyes may produce irritation with redness and discomfort.
Dermal or Respiratory Sensitization	None anticipated from normal handling of this product. However, in clinical use, intravenous administration has resulted in "red-man" syndrome, a condition characterized by erythema, flushing, or rash over the face and upper torso, and sometimes by hypotension and shock-like symptoms. The effect appears to be due in part to the release of histamine and is usually related to rapid infusion. In addition, hypersensitivity reactions occur in about 5% of patients and may include rashes, fever, chills, and rarely, anaphylactoid reactions, exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, and vasculitis.
Reproductive Effects	None anticipated from normal handling of this product. Developmental toxicology studies in rats and rabbits were performed at dosages up to 200 and 120 mg/kg/day, respectively. No developmental toxicity was observed in the rat even in the presence of maternal toxicity. In the rabbit, reduction in fetal weight was noted at the highest dose, which was higher than the dose (80 mg/kg) that produced maternal toxicity.
Mutagenicity	Vancomycin hydrochloride was not mutagenic in bacterial or mammalian cells.
Carcinogenicity	Long-term carcinogenicity studies in animals have not been conducted with vancomycin hydrochloride.
Carcinogen Lists	**IARC:** Not listed **NTP:** Not listed **OSHA:** Not listed
Specific Target Organ Toxicity – Single Exposure	NA
Specific Target Organ Toxicity – Repeat Exposure	Based on clinical use, possible target organs include the auditory system, the hematopoietic system, and the kidneys.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity	Not determined for product.
Persistence/Biodegradability	Not determined for product.
Bioaccumulation	Not determined for product.
Mobility in Soil	Not determined for product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
Container Handling and Disposal	Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
ICAO/IATA STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
IMDG STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

US TSCA Status	Exempt
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US PROP 65 (Calif.)	Not listed

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

GHS/CLP Classification*

*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user.

Hazard Class	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA

Prevention

Do not breathe vapor or spray
Contaminated work clothing must not be allowed out of the workplace
Wear protective gloves
Wash hands thoroughly after handling

Response

Get medical attention if you feel unwell.

IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention.

IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention.

Wash contaminated clothing before reuse.

15. REGULATORY INFORMATION: continued

EU Classification*	*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.
Classification(s)	NA
Symbol	NA
Indication of Danger	NA
Risk Phrases	NA
Safety Phrases	S23: Do not breathe vapor/spray S24: Avoid contact with the skin S25: Avoid contact with eyes S37/39 Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD_{50}	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
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