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Section 1 - Identification

- (a) **Product Identifier:** Vancomycin Hydrochloride for Injection, USP (500 mg per vial and 1 g per vial)
- (b) **Product Code:** 70860-104, 70860-105
- Common/Trade Name:** Vancomycin Hydrochloride
- Chemical Name:** 3S- [3R*,6S*(S*),7S*,22S*,23R*,26R*,36S*,38aS*]-3-(2-Amino-2-oxoethyl)-44-[[2-O-(3- amino-2,3,6-trideoxy-3-C-methyl- α -L-lyxo-hexopyranosyl)- β -D-glucopyranosyl]oxy]-10,19-dichloro-2,3,4,5,6,7,23,24,25,26,36,37,38,38a-tetradecahydro-7,22,28,30,32-pentahydroxy-6-[[4-methyl-2-(methylamino)-1-oxopentyl]amino]-2,5,24,38,39-pentaoxo-22H-8,11:18,21-dietheno-23,36-(iminomethano)-13,16:31,35-dimetheno-1H,16H-[1,6,9] oxadiazacyclohexadecino[4,5-m][10,2,16]-benzoxadiazacyclotetracosine-26-carboxylic acid, monohydrochloride
- Chemical Family:** Antibiotic
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vials
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

Section 2 - Hazards Identification


- (a) **Classification:** **GHS Classifications:**
Skin sensitization (Category 1)


HMIS Rating

Health Hazard	2
Flammability	0
Physical Hazard	0


NFPA Rating

Health Hazard	2
Fire Hazard	0
Reactivity Hazard	0

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(b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):	(c) Description of Hazards:
<u>Signal Word:</u> <u>Symbol</u>	- WARNING 
H317	<u>GHS Hazard Statements:</u> - May cause an allergic skin reaction
P261 P272 P280 P302 + P352 P321 P333 + P313 P363 P501	<u>GHS Precautionary Statements:</u> - Avoid breathing dust/fume/gas/mist/vapors/spray - Contaminated work clothing should not be allowed out of the workplace - Wear protective gloves - IF ON SKIN: Wash with plenty of soap and water - Specific treatment (see supplemental first aid instructions on this label) - If skin irritation or rash occurs: Get medical advice/attention - Wash contaminated clothing before use - Dispose of contents/container to an approved waste disposal plant

(d) Unknown Acute Toxicity N/A

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Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure 500 mg/unit	% Composition or other measure 1 g/unit	(c) CAS No.	(d) Impurities / Stabilizing Additives
3S- [3R*,6S*(S*),7S*,22S*,23R*,26R*,36S*,38aS*]-3-(2-Amino-2-oxoethyl)-44-[[2-O-(3-amino-2,3,6-trideoxy-3-C-methyl- α -L-lyxohexopyranosyl)- β -D-glucopyranosyl]oxy]-10,19-dichloro-2,3,4,5,6,7,23,24,25,26,36,37,38,38a-tetradecahydro-7,22,28,30,32-pentahydroxy-6-[[4-methyl-2-(methylamino)-1-oxopentyl]amino]-2,5,24,38,39-pentaoxo-22H-8,11:18,21-dietheno-23,36-(iminomethano)-13,16:31,35-dimetheno-1H,16H-[1,6,9]oxadiazacyclohexadecino[4,5-m][10,2,16]-benzoxadiazacyclotetracosine-26-carboxylic acid, monohydrochloride	Vancomycin Hydrochloride	500 mg/unit	1 g/unit	1404-93-9	N/A
Water	Water for Injection	q.s. to 5 mL	q.s. to 10 mL	7732-18-5	N/A

Section 4 - First Aid Measures

Eye Exposure: Hold eyelids open and flush with a steady, gentle stream of water for 15 minutes. See an ophthalmologist (eye doctor) or physician immediately.

Skin Exposure: Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention in irritation develops.

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Ingestion: Do not induce vomiting. Call a physician or poison control center. If available, administer activated charcoal (6-8 heaping teaspoons) with two or three glasses of water. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.

Injection: See patient package insert in shipping carton for complete information.

Inhalation: Move individual to fresh air, get medical attention if breathing difficulty occurs. If not breathing, provide artificial respiration assistance (mouth-to-mouth) and call a physician immediately.

Notes to Physician: Vancomycin – Supportive care is advised, with maintenance of glomerular filtration. Vancomycin is poorly removed from the blood by dialysis. Hemofiltration and hemoperfusion with polysulfone resin have been reported to result in increased vancomycin clearance. See patient package insert in shipping carton for complete information.

Section 5 –Fire-fighting Measures


- (a) **Extinguishing Media** Use water, carbon dioxide, dry chemical, foam or Halon.
- (b) **Hazardous Combustion Products:** As a finely divided material, may form dust mixtures in air which could explode if subjected to an ignition source.
- (c) **Special Protective Equipment / Precautions:** Not established

Section 6 - Accidental Release Measures

Spill: Wear protective equipment, including eye protection, to avoid exposure. Vacuum material with appropriate dust collection filter in place. If vacuum is not available, lightly mist material and remove by sweeping or wet wiping.

Release to Air: Be aware of potential dust explosion when using electrical equipment.

Release to Water: Refer to local water authority. Drain disposal is not recommended; refer to local, state, and federal disposal guidelines.

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Section 7 - Handling and Storage

General Handling: Avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Use of a designated area is recommended for handling of potent materials.

Storage Conditions: Prior to reconstitution, store dry powder at 20° -25°C (68°-77°F) [See USP Controlled Room Temperature.] Follow instructions provided in packaging.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits


Compound	Issuer	Type	Exposure Limit
Vancomycin Hydrochloride	OSHA	PEL	NE
	ACGIH	TLV	NE
	----	STEL	NE

(b) Engineering Controls

Ventilation: Laboratory fume hood or local exhaust ventilation

(c) Individual Protection Measures

Respiratory Protection:	Use an approved respirator.
Eye Protection:	Chemical goggles and/or face shield
Skin Protection:	Chemical-resistant gloves and body covering to minimize skin contact.
Other Protective Equipment:	If handled in a ventilated enclosure, as in a laboratory setting, respiratory and goggles or face shield may not be required. Safety glasses are always required.
Additional Exposure Precautions:	In production settings, airline-supplied-hood-type respirators are preferred. Shower and change clothing if skin contact occurs.


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Section 9 - Physical and Chemical Properties

(a)	Appearance	Off-White/Tan Lyophilized Powder
(b)	Odor	No Odor
(c)	Odor Threshold	None
(d)	pH	2.5 – 4.5
(e)	Melting Point:	Decomposes when heated
(f)	Initial Boiling Point:	Not available
(g)	Flash Point	Not available
(h)	Evaporation Rate:	Not available
(i)	Flammability	Not available
(j)	Upper Lower Flammability or Explosion Limits	Not available
(k)	Vapor Pressure:	Not available
(l)	Vapor Density:	Not available
(m)	Relative Density	Not available
(n)	Solubility(ies)	Soluble in water (50 mg/mL)
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not available
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

Section 10 - Stability and Reactivity

(a)	Reactivity	Not Available
(b)	Chemical Stability	Stable under standard use and storage conditions.
(c)	Possibility of Hazardous Reactions	No hazardous polymerization
(d)	Conditions to Avoid	Strong oxidizing agents.
(e)	Incompatible Materials	May react with strong oxidizing agents (e.g., peroxide, permanganates, nitric acid, etc.)
(f)	Hazardous Decomposition Products	May emit toxic fumes when heated to decomposition.

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Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Inhalation and skin contact
(b)	Symptoms related to the physical, chemical and toxicological characteristics	In clinical use, this material is used as an antibiotic to treat infection. Possible target organs include the ears, kidneys, fetus, skin, eyes, blood and cardiovascular system.
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	Clinical data suggests the following: nausea, abnormal kidney function, decreased blood pressure, altered hematology profile, allergic reactions.

(d) Acute Toxicity


Component	Type	Route	Species	Dosage
Vancomycin Hydrochloride	LD ₅₀	Oral	Mouse	5000 mg/kg
Vancomycin Hydrochloride	LDLo	Intravenous	Man	43 mg/kg
Vancomycin Hydrochloride	LD ₅₀	Oral	Rat	>10000 mg/kg
Vancomycin Hydrochloride	LD ₅₀	Intraperitoneal	Rat	2218 mg/kg
Vancomycin Hydrochloride	LD ₅₀	Intravenous	Rat	319 mg/kg
Vancomycin Hydrochloride	LD ₅₀	Subcutaneous	Mouse	>5 mg/kg
Vancomycin Hydrochloride	LD ₅₀	Intraperitoneal	Mouse	1734 mg/kg
Vancomycin Hydrochloride	LD ₅₀	Intravenous	Mouse	489 mg/kg
Vancomycin Hydrochloride	LD ₅₀	Intraperitoneal	Guinea Pig	737 mg/kg
Vancomycin Hydrochloride	LD ₅₀	Dermal	Rabbit	>500 mg/kg
Vancomycin Hydrochloride	LC ₅₀	Inhalation	Rat	3080 mg/kg, 1hr

(e) Hazardous Chemical Listings

NTP: Not Listed

IARC: Not Listed

OSHA: Not Listed

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Section 12 - Ecological Information

(a)	Ecotoxicity	No applicable ecological information found.
(b)	Persistence and degradability	No applicable ecological information found.
(c)	Bioaccumulative potential	No applicable ecological information found.
(d)	Mobility in soil	No applicable ecological information found.
(e)	Other Adverse Effects	No applicable ecological information found.

Section 13 - Disposal Considerations

Disposal should be performed in accordance with the federal, state or local regulatory requirements.


Section 14 - Transport Information

(a)	UN Number	Not available
(b)	UN Proper Shipping Name	Not available
(c)	Transport Hazard Class(es)	Not available
(d)	Packing Group	Not available
(e)	Environmental Hazards	Not available
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not available
(g)	Special Precautions	Not available

DOT: Not regulated
ICAO/IATA: Not regulated
IMDG: Not regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

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U.S. Regulations:

TSCA - No
CERCLA - Not on this list
SARA 302 - Not on this list
SARA 313 – Not on this list
SARA 311/312 – Not Listed
OSHA Substance Specific - No

California Proposition 65 – Not Listed

Section 16 - Other Information


As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Athenex Pharmaceutical Division
10 N. Martingale Road, Suite 230
Schaumburg, IL 60173
847-886-9515

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances

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ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMDG	International Maritime Dangerous Goods
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System

Signature Manifest

Document Number: SDS008

Revision: 01

Title: Vancomycin Hydrochloride for Injection, USP (500 mg per vial and 1 g per vial)

All dates and times are in Eastern Standard Time.

SDS008

Change Request

Name/Signature	Title	Date	Meaning/Reason
Michael Scribner (MSCRIBNER)	CORPORATE QA MANAGER	24 Jan 2017, 04:33:31 PM	Approved

Dept Approval

Name/Signature	Title	Date	Meaning/Reason
Tom Moutvic (TMOUTVIC)	VP of Regulatory Affairs	26 Jan 2017, 07:36:24 AM	Approved

Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	26 Jan 2017, 11:12:21 AM	Approved