SAFETY DATA SHEET

Date of Original Issue: May 10, 2012
Revision Number: 1
Revision Date: January 12, 2015

SECTION 1: Identification of the substance/mixture and of the company/undertaking

1.1 PRODUCT IDENTIFIER

Product name: Vancomycin Hydrochloride for Injection
REACH reg.# : Medicinal product, the mixture does not legally require an SDS and REACH pre-registration

1.2 RELEVANT IDENTIFIED USES OF THE SUBSTANCE OR MIXTURE AND USES ADVISED AGAINST

Antibiotic

Product Formulation Name: Vancomycin Hydrochloride for Injection
Chemical Family: Tricyclic glycopeptide
Synonyms: Vancomycin

1.3 DETAILS OF THE SUPPLIER OF THE SAFETY DATA SHEET

Xellia Pharmaceuticals ApS
Dalslandsgade 11
2300 Copenhagen S
Denmark

Responsible person for the safety data sheet (e-mail): sales@xellia.com

1.4 EMERGENCY TELEPHONE NUMBER

Xellia:	32 64 5500 in Denmark
Xellia:	+ 45 32 64 5500 outside of Denmark
Poison Control Center (USA):	877 800 5553
CANUTEC (Canadian Transportation):	613 996 6666
CHEMTREC (USA Transportation):	800 424 9300
UN #:	No applicable information found

COMMENTS: To the best of our knowledge, this MSDS conforms to the requirements of USA OSHA 29 CFR 1910.1200, 1907/2006/EC, 453/2010/EC and Canadian Hazardous Products Act. You are urged to consider laws and regulations applicable to your state and country.

SECTION 2: HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW

This is a medicinal product that may affect body functions. When inside vials the hazard is considered negligible.

2.1 CLASSIFICATION OF THE SUBSTANCE OR MIXTURE

CLP: Eye Irrit. 2;H319 (Causes serious eye irritation) STOT SE 3;H335 (May cause respiratory irritation) Skin Irrit. 2;H315 (Causes skin irritation) Skin Sens. 1;H317 (May cause an allergic skin reaction)

2.2 LABEL ELEMENTS:

Contents: Vancomycin hydrochloride

WARNING

H315: Causes skin irritation.
H317: May cause an allergic skin reaction.
H319: Causes serious eye irritation.
H335: May cause respiratory irritation.

P261: Avoid breathing dust/fume/gas/mist/vapors/spray.
P280: Wear protective gloves/protective clothing/eye protection/face protection.
P305+P351+P338: IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

2.3 OTHER HAZARDS:
None known.
PBT/vPvB: The substance is not considered PBT/vPvB according to criteria in Annex XIII.

SECTION 3: Composition/information on ingredients

3.1 SUBSTANCES:

Active Ingredient Name: Vancomycin Hydrochloride

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

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

Comments: Product composition ranges shown are typical values for health, safety and environmental use and are not intended as specifications.

SECTION 4: First aid measures

4.1 DESCRIPTION OF FIRST AID MEASURES:
Eye contact: Flush eyes for 15 minutes with plenty of water. If irritation persists or signs of toxicity occur, seek medical attention.
Skin contact: Remove contaminated clothing and clean before reuse. Wash all exposed areas of skin with plenty of soap and water. Get medical attention if irritation or rash develops.
Ingestion: Do not induce vomiting. Call a physician or poison control center. Do not give anything by mouth to an unconscious person. Immediately transport to a medical care facility and see a physician.
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.

SECTION 5: Firefighting measures

5.1 EXTINGUISHING MEDIA:
Water, carbon dioxide, dry chemical, foam, or other alternatives.

5.2 SPECIAL HAZARDS ARISING FROM THE SUBSTANCE OR MIXTURE:
General hazards: May be combustible at high temperature.
Hazardous combustion products: Oxides of carbon and nitrogen and corrosive hydrogen chloride.
Flash point and method: No applicable information identified.
Flammable limits: No applicable information identified.
Auto ignition temperature: No applicable information identified.
Flammable class: No applicable information identified.
Sensitivity to static charge: No applicable information identified.

5.3 ADVICE FOR FIREFIGHTERS:
No applicable information identified. Use water spray to cool fire-exposed containers and structures.

SECTION 6: Accidental release measures

6.1 PERSONAL PRECAUTIONS, PROTECTIVE EQUIPMENT AND EMERGENCY RESPONSE:
Material intended clinical uses only. Handle all pharmaceutical products in a way that will avoid contact with and inhalation of dust, fumes, mists, and / or vapors associated with the product.

6.2 ENVIRONMENTAL PRECAUTIONS:
Water spill: Do not empty into drains.
Land spill: Vacuum material with appropriate dust collection in place. Be aware of potential for dust explosion when using electrical equipment. If a vacuum is not available, lightly mist material and remove by sweeping or wet wiping. Wear appropriate equipment including eye protection, to avoid exposure.
Release notes: If the spill could potentially enter any waterway, including intermittent dry creeks, contact the local authorities. In the USA, contact the USA Coast Guard National Response Center toll free 800 424 8802.

6.3 METHODS AND MATERIALS FOR CONTAINMENT AND CLEANING UP:
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

6.4 REFERENCES TO OTHER SECTIONS:
See section 1 for emergency contact information, section 8 for personal protective equipment details, and section 13 for disposal information.

SECTION 7: Handling and storage

7.1 PRECAUTIONS FOR SAFE HANDLING:
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.

Work hygienic practices: Facilities storing or using this material should be equipped with emergency eyewash. Good personal hygiene practices should always be followed.

7.2 CONDITIONS FOR SAFE STORAGE, INCLUDING ANY INCOMPATIBILITIES:
For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert. Keep dry, and away from sources of ignition. Below 8°C (46°F).

7.3 SPECIFIC END USES:
See section 1.

SECTION 8: Exposure controls/personal protection

8.1 CONTROL PARAMETERS:
OSHA'S hazardous components (29 CFR 1910.1020)

		EXPOSURE LIMITS AND GUIDELINES					
		OSHA PEL		ACGIH TLV		OTHER OEL	
		ppm	mg/m^3	ppm	mg/m^3	ppm	mg/m^3
Vancomycin hydrochloride [CAS 1404-93-9]	**TWA**	NL	NL	NL	NL	NL	0.1
	STEL	NL	NL	NL	NL	NL	NL

Other country exposure limits: Not listed.

8.2 EXPOSURE CONTROLS:
Appropriate engineering controls: Respiratory protection is normally not needed during intended product use. If dust is generated, provide local exhaust ventilation to control airborne levels below the OEL listed above.

Personal protective equipment:
Eyes and face: Wear safety glasses with side shields or goggles as appropriate when handling this material.
Skin: Chemical resistant gloves (nitrile or latex) and body covering.
Respiratory: Use an approved respirator suitable to provide level of protection required.

Comments: This product is not specifically listed by OSHA as hazardous. However, this material may cause sensitization or an allergic response with minimal exposure. Under conditions of overexposure, the material may be hazardous.

SECTION 9: Physical and chemical properties

9.1 INFORMATION ON BASIC PHYSICAL AND CHEMICAL PROPERTIES:
Physical state: Powder (Solid in vials)
Appearance: White to off-white powder in vials.
Color: White to off-white.
Odor: Odorless.
Odor threshold: Not relevant.
pH: 2.5-4.5 (5% aqueous solution)
Vapor pressure: No applicable information found.
Vapor density: No applicable information found.
Evaporation rate: No applicable information found.
Freezing point: Not applicable.
Melting point: Decomposes when heated.
Boiling point: No applicable information found as this is a powder.
Flash point: No applicable information found.
Decomposition temperature: No applicable information found.
Flammability: No applicable information found.
Upper/lower flammability or explosive limits (vol-%): No applicable information found.
Auto-ignition temperature: No applicable information found.
Soluble in water: Soluble.
Density: No applicable information found.
Specific gravity: No applicable information found as this is a powder.
Viscosity: No applicable information found.
Explosive properties: No applicable information found.

Oxidising properties: No applicable information found.
Molecular formula: C66 H75 Cl2 N9 O24 H Cl
Molecular weight: 1485.73
Coefficient of oil and water: No applicable information found.

9.2 OTHER INFORMATION:
None relevant.

SECTION 10: Stability and reactivity

10.1 REACTIVITY: No applicable information found.
10.2 CHEMICAL STABILITY: Stable at normal temperatures and pressures.
10.3 POSSIBILITY OF HAZARDOUS REACTIONS: No applicable information found.
10.4 CONDITIONS TO AVOID: Avoid heat, moisture, and sunlight.
10.5 INCOMPATIBLE MATERIALS: May react with strong oxidizing agents (e.g., peroxides, permanganates, nitric acid, etc.)
10.6 HAZARDOUS DECOMPOSITION PRODUCTS: If heated to very high temperatures, the product may form hazardous decomposition products such as oxides of carbon and nitrogen and corrosive hydrogen chloride.

SECTION 11: Toxicological information

11.1 INFORMATION ON TOXICOLOGICAL EFFECTS:
Acute Toxicity - Not determined for the product formulation. Information for the ingredients is as follows:

Acute dermal LD_{50}: >500 mg/kg, rabbit; no deaths or toxicity
Acute oral LD_{50}: >5000 mg/kg, rat (non-toxic); leg weakness, diarrhea
Acute inhalation LC_{50}: >3080 mg/m^3, rat (1 hour); no deaths, increased activity
Eye effects: Irritant (rabbit)
Skin effects: Irritant (rabbit)
Sensitization: Sensitizer (human)
Target organs: Nervous system, heart, blood, kidney, and digestive system.
Carcinogenicity:
Listed by IARC: No **Listed by NTP:** No **Listed by OSHA:** No
Mutagenicity: Negative (in-vitro mouse lymphoma forward mutation assay; rat hepatocyte unscheduled DNA synthesis; in-vivo Chinese hamster sister chromatid exchange and mouse micronucleus assay)
Reproductive effects: No applicable information found.
Teratogenic effects: Negative in rats and rabbits.

SECTION 12: Ecological information

12.1 TOXICITY: No applicable information found.
12.2 PERSISTENCE AND DEGRADABILITY: No applicable information found.
12.3 BIOACCUMULATIVE POTENTIAL: No applicable information found.
12.4 MOBILITY IN SOIL: No applicable information found.
12.5 RESULTS OF PBT AND vPvB ASSESSMENT: The substance is not considered PBT/vPvB according to criteria in Annex XIII.
12.6 OTHER ADVERSE EFFECTS: The substance is possibly harmful for the aquatic environment, due to is antibiotic properties.

SECTION 13: Disposal considerations

13.1 WASTE TREATMENT METHODS:
Disposal (includes Spills, Empty Containers): Dispose of any cleanup materials and waste residue according to applicable laws and regulations.

SECTION 14: Transport information

14.1 UN NUMBER: Not regulated.
14.2 UN PROPER SHIPPING NAME: Not relevant.
14.3 TRANSPORT HAZARD CLASS(ES): Not relevant.
14.4 PACKING GROUP: Not relevant.
14.5 ENVIRONMENTAL HAZARDS: None.

14.6 SPECIAL PRECAUTIONS FOR USER: None.
14.7 TRANSPORT IN BULK ACCORDING TO ANNEX II MARPOL 73/78 AND THE IBC CODE: Not relevant.

USA DOT (DEPARTMENT OF TRANSPORTATION)
Proper Shipping Name: Not regulated
CANADA TRANSPORT OF DANGEROUS GOODS
Proper Shipping Name: Not regulated.
AIR (ICAO/IATA)
Proper Shipping Name: Not regulated.
VESSEL (IMO/IMDG)
Proper Shipping Name: Not regulated.
EUROPEAN TRANSPORTATION:
ADR/RID HAZARD CLASSIFICATION: Not regulated.
U.S. CUSTOMS HARMONIZATION NUMBER: Not regulated.

SECTION 15: Regulatory information

15.1 SAFETY, HEALTH AND ENVIRONMENTAL REGULATION/LEGISLATION SPECIFIC FOR THE SUBSTANCE OR MIXTURE:

This section contains selected regulatory information for possible use by Xellia Pharmaceuticals. This section is not intended to be a complete listing of all applicable regulations. You are urged to consider laws and regulations applicable to your state and country.

EUROPEAN COMMUNITY

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH),

Council Directive 94/33/EC of 22 June 1994 on the protection of young people at work:
Must not be used by persons under 18 years of age.

Council Directive 92/85/EEC of 19 October 1992 on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding:
Not regulated. However, it is recommended, that the employer assess the working conditions and, if there is any risk to the safety or health and any effects on the pregnancy or breastfeeding of workers, take the necessary measures to adjust the working conditions.

Implementation of directive 2001/82/EC of the European Parliament and of the council of 6 November 2001 in the Community code relating to veterinary medical products:
Denmark: The Danish Medicines Agency (Lægemiddelstyrelsen) must be notified that this substance is produced, imported, exported, stored, sold, delivered, packed, possessed or in other ways handled in Denmark (Bekendtgørelse nr. 1226 af 7. December 2005 om omgang med visse stoffer og produkter hvis indhold kan anvendes som lægemidler til dyr.).
For other countries: Please contact national authorities regarding notification of the substance.

UNITED STATES FEDERAL REGULATIONS

Superfund Amendments and Reauthorization Act (SARA) Title III 311/312 hazard categories:
Fire: No **Pressure generating:** No **Reactivity:** No **Acute:** Yes **Chronic:** No

313 Reportable Ingredients: Not listed.
Title III notes:

Comprehensive Response, Compensation, and Liability Act (CERCLA)
CERCLA RQ: Not listed

Toxic Substances Control Act (TSCA)
TSCA Regulatory: Not listed.

National Response Center: US Coast Guard National Center Response Telephone number is 800 424 8802.

UNITED STATES STATE REGULATIONS

California Proposition 65: Not listed.

CANADA

Workplace Hazardous Material Information System (WHMIS) hazard symbol and classification
WHMIS Controlled: Not regulated.

Canadian Environmental Protection Act: Not listed.

15.2 CHEMICAL SAFETY ASSESSMENT:

No CSR.

SECTION 16: Other information'

Reason for issue: EC regulation, REACH and CLP

Contact Information: See Section 1

Revision summary: 1-16

	HMIS RATING	NFPA RATING
Health	ND	ND
Flammability	ND	ND
Physical hazard	ND	ND
Personal protection	ND	ND
Incompatibilities	ND	ND

Data sources: Micromedex DrugDex; Mosby's Drug Consult; Physicians Desk Reference.

Disclaimer: Information given herein is offered in good faith as accurate, but without guarantee. Conditions of use and suitability of the product for particular uses are beyond our control; all risks of use of the product are therefore assumed by the user. Nothing is intended as a recommendation for uses that infringe valid patents or as extending license under valid patents. Appropriate warnings and safe handling procedures should be provided to handlers and users.

Glossary:

ACGIH – American Conference of Governmental Hygienists
AIHA – American Industrial Hygiene Association
BEI – Biological Exposure Index
CAS – Chemical Abstract Service Registry Number
CSR – Chemical Safety Report
CERCLA – Comprehensive Environmental Response Compensation and Liability Act of 1989
CHEMTREC – Chemical Transportation Emergency Center
DOT – Department of Transportation (USA)
EC – European Community
EINECS – European Inventory of Existing Chemical Substances
ELINCS - European List of New Chemical Substances
EPA – Environmental Protection Agency
FDA – United States Food and Drug Administration
HEPA- High Efficiency Particulate Air (Filter)
HMIS – Hazardous Material Information System
IARC- International Agency on Research for Cancer
ICAO/IATA – International Civil Aviation Organization/International Air Transport Association
IMO – International Maritime Organization
LEL – Lower Explosive Limit
MSDS – Material Safety Data Sheet
MSHA – Mine Safety and Health Administration
NA – Not Applicable
NADA – New Animal Drug Application
NAIF – No Applicable Information Found
NCI – National Cancer Institute
ND – Not Determined
NFPA – National Fire Protection Association
NIOSH – National Institute for Occupational Health and Safety
NL – Not Listed
NOS – Not Otherwise Specified
NTP – National Toxicology Program
OEL – Occupational Exposure Limit
OSHA – Occupational Safety and Health Administration
PEL – Permissible Exposure Limit (USA)
RCRA – Resource Conservation and Recovery Act
RQ – Reportable Quantity
RTECS – Registry of Toxic Effects of Chemical Substances
SARA – Superfund Amendments and Reauthorization Act
STEL – Short Term Exposure Limit
TLV – Threshold Limit Value
TPQ – Threshold Planning Quantity
TSCA – Toxic Substances Control Act
TWA – Time Weighted Average
UEL – Upper Explosive Limit
UN – United Nations
WEEL – Workplace Environmental Exposure Level (USA - AIHA)

GDP Product Handling Instruction for Vancomycin HCl for Injection, USP

100grmas per Pharmacy Bulk Package Bag

PART 1 Storage and preparation for shipping: to be filled by Xellia

PART 2 Receiving acceptance: to be filled by Customer

PART 1

The purpose of this document is to provide instructions for the secondary and tertiary packaging and data logger start-up and installation prior to storage and shipping.

1 Product and Shipping Data

Product name:	**Vancomycin HCl for Injection, USP**
Size of Vial:	**100grmas per Pharmacy Bulk Package Bag**
Item number:	450301004
Reference Number:	**SO 17000706**
Manufacturer:	**Xellia Pharmaceuticals ApS, CPH**
Ship from:	**Xellia Pharmaceuticals ApS** **Dalslandsgade 11** **2300 Copenhagen S Denmark**
Customer & Ship to:	**Samson Medical Technologies, L.L.C.** **2050 Springdale Road, Suite 400** **Cherry Hill, NJ 08003**
Temperature storage conditions:	**20-25° C**
Thermal packaging option: (only if applicable)	**N/A**

2 Preparation of Shipment Details

Customer Services (CS) is responsible for preparation of shipment - except where indicated otherwise

3 Preparation for Shipping

Packaging Operations responsible except where indicated otherwise

3.1 Ensure each shipper box is labelled with approved shipper label.

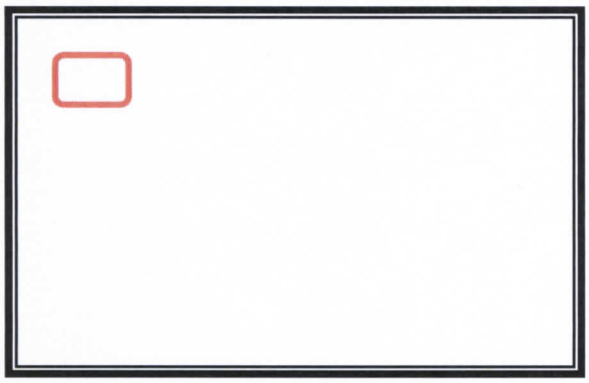
Packaging Configuration

Shippers are placed on UK pallet with size 1200 x 1000mm.

Pallet shown from above showing where data logger is to be placed.

Data logger to be placed on top of pallet.

1 Data logger is to be placed on top of each pallet



4 Preparation for Shipping – Packaging and Data logger Placement

No.	Tasks	Responsibility
4.1	Check pallets are banded and secure (edge protection where bands pass round corners of shippers / outer box)	Xellia WH
4.2	Pallets to be stored at instructed temperature until further shipment to customer	Xellia WH
4.3	**Data logger Options:**	
	Create the shipment in ColdStream	Xellia CS
	Record the data logger serial numbers into ColdStream	Xellia CS
	Start the data loggers	Xellia WH
	Data loggers must be placed in special boxes and boxed labelled for easy identification	Xellia WH
	1 Data logger is to be placed on top of each pallet	Xellia WH
	The serial number "stickers" on the data loggers should be affixed in attachment 1	Xellia CS
4.4	Control of Pallet/Address label against shipping document	Xellia WH

4.5	**Control of the Storage Temperature label at 20-25° C** and **"Do not over-stack"** labels or label tape in visual positions on the pallet	Xellia WH
4.6	Shipping document is pasted onto a pallet	Xellia WH
4.7	Shipment to Customer is arranged and shipping document and GDP Product Handling Instruction Part 2 are provided to customer via e-mail	Xellia CS
4.8	Warehouse to ensure all section of GDP check list is completed	Xellia WH
4.9	Temperature data files (.pdf and .ttv) from data loggers to be uploaded in ColdStream	Xellia CS

5 Document References

5.1 The following documents provide guidance for processes directly associated with the GDP Product Handling Instruction

Title	QMS Number
Order Handling Procedure	104.15.4002.0002
Use of ColdStream	104.15.4002.0004
Use of Sensitech TempTale IV Data loggers	104.15.4002.0009
Use of customer specific data loggers(if any)	
GDP Product handling Procedure	072

6 Shipping Waypoint Summary

6.1 Shipping lane:

From Xellia Copenhagen to Philadelphia - According to Leman Risk Assessment.

CPH-FRA - LH

FRA-PHL – LH