

## SAFETY DATA SHEET

Date of Original Issue: 30SEP2005

Revision Number: 10

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### SECTION 1: Identification Of The Substance/Mixture And Of The Company/Undertaking

#### 1.1 Product identifier

**Product name:** Vancomycin hydrochloride API  
**CAS #:** 1404-90-6  
**EC/List #:** 215-772-6  
**INDEX #:** Not listed  
**REACH reg. #:** Not listed

#### 1.2 Relevant identified uses of the substance or mixture

**Product Name:** Vancomycin hydrochloride API  
**Product Use:** Pharmaceuticals – Antibiotic  
**Synonyms:** Vancomycin

#### 1.3 Details of the responsible party of the safety data sheet

**Manufacturer**  
Xellia Pharmaceuticals ApS  
Dalslandsgade 11  
2300 Copenhagen S  
Denmark  
+45 3264 5500  
Responsible person for the safety data sheet (e-mail): sales@xellia.com

#### 1.4 Emergency telephone number

Poison Control Center (USA): +1 877 800 5553  
CHEMTREC (USA Transportation): +1 800 424 9300  
CANUTREC (Canadian Transportation): +1 613 996 6666  
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

#### 2.1 Classification of the substance or mixture

Eye Irritation – Category 2; Specific Target Organ Toxicity (Single Exposure) - Category 3; Skin Irritation – Category 2; Skin Sensitization – Category 1

#### 2.2 Label elements

Content: Vancomycin

Content:



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.  
P264: Wash hands thoroughly after handling.  
P265: Do not touch eyes.  
P271: Use only outdoors or in a well-ventilated area.  
P272: Contaminated work clothing should not be allowed out of the workplace.  
P280: Wear protective gloves/protective clothing/eye protection/face protection.  
P302+P352: If on skin: Wash with plenty of water  
P304+P340: If inhaled: Remove person to fresh air and keep comfortable for breathing.

P305+P351+P338: If in eyes: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.  
P319: Get medical help if you feel unwell.  
P321: Specific treatment (see section 4)  
P332+P317: If skin irritation occurs: Get emergency medical help.  
P333+P313: If skin irritation or rash occurs: Get medical advice/attention.  
P337+P317: If eye irritation persists: Get emergency medical help.  
P362+P364: Take off contaminated clothing and wash it before reuse.  
P403+P233: Store in a well-ventilated place. Keep container tightly closed.  
P405: Store locked up.  
P501: Dispose of contents/container appropriately

## 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 component	Hazards Classification	CAS #	EU/List #
Vancomycin Hydrochloride	Eye Irritation – Category 2; Specific Target Organ Toxicity (Single Exposure) - Category 3; Skin Irritation – Category 2; Skin Sensitization – Category 1	1404-90-6	215-772-6

Comments: N/A

## SECTION 4: First Aid Measures

### 4.1 Description of first aid measures

**Eye contact:** Flush eyes for 15 minutes with plenty of water. Get medical attention immediately.

- 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.

#### **4.2 Most important symptoms and effects, both acute and delayed**

**Symptoms and Effects of Exposure:** For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

**Medical Conditions Aggravated by Exposure:** Hypersensitivity (allergy) to vancomycin hydrochloride and other tricyclic glycopeptides

#### **4.3 Indication of any immediate medical attention and special treatment needed**

In case of discomfort or unconsciousness: Show this safety data sheet to a physician or emergency center, treat symptomatically.

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### **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. Fine particles (such as dust and mists) may fuel fires/explosions.
- Hazardous combustion products:** Emits toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, and chlorides.
- Unsuitable extinguishing media:** None
- Specific methods:** Not available

#### **5.3 Advice for firefighters**

As in any fire, wear self-contained breathing apparatus pressure-demand, MSHA/NIOSH (approved or equivalent) and full protective gear.

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### **SECTION 6: Accidental Release Measures**

#### **6.1 Personal precautions, protective equipment, and emergency response**

Wear personal protective equipment to avoid exposure – see section 8. Avoid generation of dust.

#### **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 +1 800 424 8802.

### 6.3 Methods and materials for containment and cleaning up

Contain dry material by lightly misting with water, followed by sweeping carefully so as not to generate dust, or vacuuming. Ensure the vacuum is fitted with an appropriate dust filter so dust is not re-introduced into the air. Be aware of the potential for dust explosion when using electrical equipment.

### 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

**For large quantities:** Engineering controls are recommended to ensure adequate ventilation such that exposures do not exceed exposure limits. With adequate ventilation respiratory protection may not be needed. In the absence of adequate ventilation, suitable respiratory protection is required. The need for additional personal protective equipment including respirators, eye and skin protection should be based on a job-specific risk assessment. Additional personal protective equipment may include chemical-resistant gloves and body covering, goggles, and face shield. Adequate eye protection is always required.

**For small quantities:** Keep dry and away from sources of ignition. Keep the bottle tightly closed when not in use.

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

### 7.2 Conditions for safe storage, including any incompatibilities

Store securely, inaccessible for unauthorized persons. Keep dry and away from sources of ignition. Store refrigerated 2-8°C (36°F -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

	<u>OSHA PEL</u>		<u>ACGIH TLV</u>		<u>OTHER OEL (TWA)</u>	
	<u>ppm</u>	<u>mg/m<sup>3</sup></u>	<u>ppm</u>	<u>mg/m<sup>3</sup></u>	<u>ppm</u>	<u>mg/m<sup>3</sup></u>
Vancomycin (CAS #: 1404-93-9)	N/A	N/A	N/A	N/A	N/A	0.2

**Other country exposure limits:** Not listed.

This product does not contain any hazardous materials with occupational exposure established by the region-specific regulatory bodies

### 8.2 Exposure controls

**Appropriate engineering controls:** 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.

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**SECTION 9: Physical And Chemical Properties****9.1 Information on basic physical and chemical properties**

<b>Physical state:</b>	Solid
<b>Appearance:</b>	Powder
<b>Color:</b>	White to off-white
<b>Odor:</b>	Odorless
<b>Odor threshold:</b>	Not Applicable
<b>pH:</b>	2.5 - 4.5
<b>Vapor pressure:</b>	Not Applicable
<b>Vapor density:</b>	Not Applicable
<b>Evaporation rate:</b>	Not Applicable
<b>Freezing point:</b>	Not Applicable
<b>Melting point:</b>	Decomposes when heated
<b>Boiling point:</b>	Not Applicable
<b>Flash point:</b>	Not Applicable
<b>Decomposition temperature:</b>	Not Applicable
<b>Flammability:</b>	Not Applicable
<b>Upper/lower flammability or explosive limits (vol-%):</b>	Not Applicable
<b>Auto-ignition temperature:</b>	Not Applicable
<b>Soluble in water:</b>	Slightly Soluble
<b>Density:</b>	Not Applicable
<b>Specific gravity:</b>	Not Applicable
<b>Viscosity:</b>	Not Applicable
<b>Explosive properties:</b>	Not Applicable
<b>Oxidizing properties:</b>	Not Applicable
<b>Molecular formula:</b>	C <sub>66</sub> H <sub>75</sub> Cl <sub>2</sub> N <sub>9</sub> O <sub>24</sub> Cl
<b>Molecular weight:</b>	1485.73
<b>Coefficient of oil and water:</b>	No applicable information found.

**9.2 OTHER INFORMATION:**

Not available.

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**SECTION 10: Stability And Reactivity****10.1 Reactivity**

No data available.

**10.2 Chemical stability**

Stable under recommended storage conditions.

**10.3 Possibility of hazardous reactions**

Hazardous polymerization has not been reported.

#### 10.4 Conditions to avoid

Incompatible materials, dust generation, excess heat, alkaline materials, strong oxidants, exposure to moist air, sunlight, or water.

#### 10.5 Incompatible materials

Strong oxidizing agents.

#### 10.6 Hazardous decomposition products

Oxides of carbon and nitrogen and corrosive hydrogen chloride.

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### SECTION 11: Toxicological Information

#### 11.1 Information on toxicological effects

**Acute dermal LD50:** >500 mg/ kg (rabbit)

**Acute oral LD50:** >5000 mg/ kg (mouse)

**Acute inhalation LC50:** No information available

**Eye effects:** Irritant

**Skin effects:** Irritant

**Sensitization:** Sensitizer

**Target organ:** Nervous system, heart, blood, kidney, and digestive system.

**Carcinogenicity:**

**Listed by IARC:** No

**Listed by NTP:** No

**Listed by OSHA:** No

**Mutagenicity:** Negative Results

**Reproductive effects:** Negative Results

**Teratogenic effects:** Negative Results

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### SECTION 12: Ecological Information

#### 12.1 Toxicity

No applicable information found. Releases to the environment should be avoided.

#### 12.2 Persistence and degradability

No applicable information found.

#### 12.3 Bio-accumulative 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 its antibiotic properties.

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## SECTION 13: Disposal Considerations

**13.1 Waste treatment methods:** Do not empty into drain. Dispose of any cleanup materials and waste residue according to applicable laws and regulations.

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## SECTION 14: Transport Information

### 14.1 UN Number

Not Regulated.

### 14.2 UN proper shipping name

Not Regulated.

### 14.3 Transport hazard class(es)

Not Regulated.

### 14.4 Packing group

Not Regulated.

### 14.5 Environmental hazards

Not Regulated.

### 14.6 Special precautions for user

Not Regulated.

### 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 Available.

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## SECTION 15: Regulatory Information

### 15.1 Safety, health, and environmental regulation/legislation specific for the substance or mixture

#### EUROPEAN COMMUNITY

**Regulation (EC) No 1272/2008** on the classification, labelling and packaging of substances and mixtures (CLP Regulation)

**Regulation (EC) No 1907/2006** of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorization 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:**

The employer shall 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:** No      **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  
+1 800 424 8802.

#### UNITED STATES STATE REGULATIONS

**California Proposition 65:** This product does not contain chemicals known to the State of California to cause cancer and birth defects or other reproductive harm.

#### 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:** Revised Document

**Contact Information:** See Section 1.

**Revision summary:** Tenth Issue. Updated format.

**Disclaimer:** Information given herein is offered in good faith as accurate, but without guarantee. Conditions of use and suitability of the product for 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 Page 7 of 7  
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)

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