

## SAFETY DATA SHEET

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### SECTION 1: Identification of the Substance/Mixture and of the Company/Undertaking

#### 1.1. Product identifier

**Product name:** VANCO READY® Vancomycin Injection

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

**Product Use:** Pharmaceutical product used as antibiotic agent

**Synonyms:** Vancomycin

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

**Manufacturer**

Inforlife SA  
Casai  
7748 Campascio  
Switzerland  
+41 81 839 20 20

**Distributor**

Xellia Pharmaceuticals  
2150 East Lake Cook Road  
Buffalo Grove, IL 60089  
USA  
+1 833 657 3519

email address for the competent person responsible for the safety data sheet: 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  
<http://apps.who.int/poisoncentres/>

### SECTION 2: Hazards Identification

#### 2.1. Classification of the substance or mixture

Not classified as hazardous according to the CLP regulation

#### 2.2. Label elements

EUH208 Contains vancomycine hydrochloride. May produce an allergic reaction.

EUH210 Safety data sheet available on request.

#### 2.3. Other hazards

The substance is not considered PBT/vPvB, or endocrine disruptive according to the criteria in the CLP regulation.

### SECTION 3: Composition/Information on Ingredients

#### 3.2. Mixtures

Active component	CAS #	EC/List #
Vancomycin Hydrochloride 0.5%	1404-93-9	604-193-8

**REACH registration:** exempted.

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## 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. 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:** None

### 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

- 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.

### 6.2. Environmental precautions

- Water spill:** Do not empty into drains.
- Release notes:** If the spill could potentially enter any waterway, including intermittent dry creeks, contact the local authorities.

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

Absorb spilled product with sand or similar materials.

### 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 TWA for an eight-hour exposure. 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.

**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. Store between 25°C (77°F) in original, unopened package or container. Product should be used within 28 days of removal from aluminum overpouch.

### 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>	
	ppm	mg/ m <sup>3</sup>	ppm	mg/ m <sup>3</sup>	ppm	mg/ m <sup>3</sup>
Vancomycin (CAS #: 1404-90-6)	N/A	N/A	N/A	N/A	N/A	0.2

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

### 8.2. Exposure controls

#### 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.

## SECTION 9: Physical and Chemical Properties

### 9.1. Information on basic physical and chemical properties

(a) **Physical state:** Liquid

(b) **Color:** Clear, colorless to light brown

- (c) **Odor:** Odorless  
(d) **Melting point/freezing point:** Below 0°C.  
(e) **Boiling point or initial boiling point and boiling range:** Above 100°C  
(f) **Flammability:** Not flammable  
(g) **Lower and upper explosion limit:** Not applicable  
(h) **Flash point:** Not applicable  
(i) **Auto-ignition temperature:** Not available  
(j) **Decomposition temperature:** Not available  
(k) **pH:** 4.5-5.5  
(l) **Kinematic viscosity:** Like water  
(m) **Solubility:** Soluble  
(n) **Partition coefficient n-octanol/water (log value):** Not available  
(o) **Vapor pressure:** Like water  
(p) **Density and/or relative density:** Above 1 g/cm<sup>3</sup>  
(q) **Relative vapor density:** Like water  
(r) **Particle characteristics:** Solution

## 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, excess heat, alkaline materials, strong oxidants.

### 10.5. Incompatible materials

Strong oxidants.

### 10.6. Hazardous decomposition products

Nitrogen oxides, carbon monoxide, and carbon dioxide.

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## SECTION 11: Toxicological Information

### 11.1. Information on toxicological effects

**Acute dermal LD50:** >500 mg/ kg (rabbit). Based on available data the classification criteria are not met.  
**Acute oral LD50:** >5000 mg/ kg (mouse). Based on available data the classification criteria are not met.  
**Acute inhalation LC50:** Based on available data the classification criteria are not met.  
**Eye effects:** Irritant  
**Skin effects:** Irritant  
**Sensitization:** Sensitizer

**Target organ:** Nervous system, heart, blood, kidney, and digestive system. Based on available data the classification criteria are not met.

**Carcinogenicity:**

**Listed by IARC:** No

**Listed by NTP:** No

**Listed by OSHA:** No

**Mutagenicity:** Negative Results Based on available data the classification criteria are not met.

**Reproductive effects:** Negative Results Based on available data the classification criteria are not met.

**Teratogenic effects:** Negative Results Based on available data the classification criteria are not met.

## 11.2. Information on other hazard

Not available

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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. Endocrine disrupting properties

No such properties are known to the substance.

### 12.7. 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 or ID 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. Maritime transport in bulk according to IMO instruments

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 UNION

**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:** Exempt

**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 is compiled because the substance is exempted.

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**SECTION 16: Other Information**

**Reason for issue:** Update to include 2020/878 EU Commission regulation. Changed the classification of the solution to not-classified because of its concentration.

**Contact Information:** See Section 1.

**Revision summary:** Fifth issue.

**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.

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