

# Material Safety Data Sheet

According to (EC) No 1907/2006 (REACH) and 1272/2008 (CLP)

## VANCOMYCINI HYDROCHLORIDUM

EN

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Revision: 03/07/2022

Version: 01



### SECTION 1: IDENTIFICATION OF THE SUBSTANCE/MIXTURE AND OF THE COMPANY/UNDERTAKING

#### 1.1 Product identifier

Product name:	Vancomycin hydrochloride Vancomycini hydrochloridum Vancomycine hydrochloride Vancomycine (chlorhydrate de) Vancomycinhydrochlorid
N° CAS:	1404-93-9
N° EC:	604-193-8

#### 1.2 Relevant identified uses of the substance/mixture and uses advised against

Identified uses:	Active Pharmaceutical Ingredient or Excipient.
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#### 1.3 Details of the supplier of the safety data sheet

Company:	Magis-Pharma NV Neerlandweg 24 2610 Wilrijk Belgium
Telephone:	(+32) (0)3 457 11 76
Email:	info@magis-pharma.be
Web page:	www.magis-pharma.be

#### 1.4 Emergency telephone number

Public utility foundation:	Belgisch Antigifcentrum	Centre Antipoisons Belge
Telephone:	(+32) (0)70 245 245	(Service 24/7)
Web page:	www.antigifcentrum.be	www.centreantipoisons.be

### SECTION 2: HAZARDS IDENTIFICATION

#### 2.1 Classification of the substance/mixture

##### Classification according to (EC) n° 1272/2008

Skin Irrit. 2	H315
Eye Irrit. 2	H319
Skin Sens. 1	H317
STOT SE3	H335

#### 2.2 Label elements

##### Labelling according to (EC) n° 1272/2008

Hazard pictogram(s):



Signal word(s): Attention

Hazard statements:

H315	Causes skin irritation
H317	May cause an allergic skin reaction.

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H319	Causes serious eye irritation.
H335	May cause respiratory irritation.
Precautionary statements:	
P261	Avoid breathing dust/fume/gas/mist/vapours/spray.
P264	Wash hands thoroughly after handling.
P271	Use only outdoors or in a well-ventilated area.
P272	Contaminated clothing should not be allowed outside 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 victim to fresh air and keep at rest in a position comfortable for breathing.
P305+P351+P338	IF IN EYES: rinse continuously with water for several minutes. Remove contact lenses if present and easy to do. Continue rinsing.
P351	Rinse cautiously with water for several minutes.
P337+P313	If eye irritation persists get medical advice/attention.
P333+P313	If skin irritation or a rash occurs: Get medical advice/attention.
P312	Call a POISON CENTER or doctor/physician if you feel unwell.
P362	Take off contaminated clothing
P363	Wash contaminated clothing before reuse.

Additional applicable label elements:



### 2.3 Other hazards

Not available.

## SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

### 3.1 Substances

Product name:	Vancomycin hydrochloride
IUPAC name:	(1S,2R,18R,19R,22S,25R,28R,40S)-48-[(2S,3R,4S,5S,6R)-3-[(2S,4S,5S,6S)-4-amino-5-hydroxy-4,6-dimethyloxan-2-yl]oxy-4,5-dihydroxy-6-(hydroxymethyl)oxan-2-yl]oxy-22-(2-amino-2-oxoethyl)-5,15-dichloro-2,18,32,35,37-pentahydroxy-19-[[[(2R)-4-methyl-2-(methylamino)pentanoyl]amino]-20,23,26,42,44-penta-oxo-7,13-dioxo-21,24,27,41,43-pentazaocatacyclo[26.14.2.2 <sup>3,6</sup> .2 <sup>14,17</sup> .1 <sup>8,12</sup> .1 <sup>29,33</sup> .0 <sup>10,25</sup> .0 <sup>34,39</sup> ]]pentaconta-3,5,8(48),9,11,14,16,29(45),30,32,34(39),35,37,46,49-pentadecaene-40-carboxylic acid;hydrochloride
Synonyms:	Vancomycin HCL Vancomycin monohydrochloride
N° CAS:	1404-93-9
N° EC:	604-193-8
Molecular Formula:	C <sub>66</sub> H <sub>76</sub> Cl <sub>3</sub> N <sub>9</sub> O <sub>24</sub>
Content:	100%

### 3.2 Mixtures

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Not applicable.

### SECTION 4: FIRST AID MEASURES

#### 4.1 Description of first aid measures

General notes:	If feeling unwell, seek medical advice (show this label if possible).
After inhalation:	If inhaled, remove to fresh air. If breathing becomes difficult, call a physician.
After skin contact:	In case of skin contact, flush with copious amounts of water for at least 15 minutes. Remove contaminated clothing and shoes. Call a physician.
After eye contact:	In case of contact with eyes, flush with copious amounts of water for at least 15 minutes. Assure adequate flushing by separating the eyelids with fingers. Call a physician.
After ingestion:	If swallowed, wash out mouth with water provided person is conscious. Call a physician.

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

Not available.

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

Not available.

### SECTION 5: FIREFIGHTING MEASURES

#### 5.1 Extinguishing media

Suitable extinguishing media:	Water spray. Carbon dioxide, dry chemical powder, or appropriate foam.
Unsuitable extinguishing media:	Not available.

#### 5.2 Special hazards arising from the substance/mixture

Hazardous decomposition products in case of fire: Carbon oxides (CO, CO<sub>2</sub>), nitrogen oxides, hydrogen chloride gas.

#### 5.3 Advice for firefighters

Surrounding fires:	Do not enter fire area without suitable protective equipment, including respiratory protection.
Protection against fire:	Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.
Hazardous combustion products:	Not available.

### SECTION 6: ACCIDENTAL RELEASE MEASURES

#### 6.1 Personal precautions, protective equipment and emergency procedures

##### For non-emergency personnel

Do not breathe dust. Provide adequate ventilation. Wear recommended personal protective equipment. Avoid spreading dust.

##### For emergency responders

Do not breathe dust. Provide adequate ventilation.

#### 6.2 Environmental precautions

Prevent entry to sewers and public waters.

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

Methods for cleaning up: Sweep up, shovel or vacuum. Limit the formation of dust.

### 6.4 Reference to other sections

Not available.

## SECTION 7: HANDLING AND STORAGE

### 7.1 Precautions for safe handling

Precautions for safe handling:	Avoid dust development.
Personal protection:	Avoid contact with eyes, skin, and clothing. Avoid prolonged or repeated exposure.
Technical protective measures:	Not available.
Handling:	Not available.

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

Storage:	Store in an airtight container. If the substance is sterile, the container is also sterile and tamper evident.
Conditions for safe storage, including any incompatibilities:	Store in a dry and well-ventilated area at a temperature of 2°C to 8°C.
Storage – away from:	Protect from light.

### 7.3 Specific end use(s)

Active Pharmaceutical Ingredient or Excipient

## SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

### 8.1 Control parameters

Not available.

### 8.2 Exposure controls

#### Appropriate engineering control

Handle in accordance with good industrial hygiene and safety practices.

#### Individual protection measures

Eye/face protection:	Safety glasses (according to European standard EN 166 or comparable)
Skin protection:	Protective clothing (with closed collar and sleeves)
Hand protection:	Wear chemical-resistant gloves according to EN 374 that protect against skin effects from powders
Respiratory protection:	Dust mask with filter type P1
Thermal hazards:	Not determined.

#### Environmental exposure control

Prevent entry to sewers and public waters.

## SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

### 9.1 Information on basic physical and chemical properties

Appearance:	White or almost white, hygroscopic powder
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Odour:	Not available.
Odour threshold:	Not available.
pH:	2.5 to 4.5
Melting/freezing point:	Not available.
Initial boiling point:	Not available.
Boiling range:	Not available.
Flash point:	Not available.
Evaporation rate:	Not available.
Flammability (solid/gas):	Not available.
Upper/lower flammability or explosive limits:	Not available.
Vapour pressure:	Not available.
Vapour density:	Not available.
Relative density:	Not available.
Solubility:	Practically insoluble in ethanol (96 per cent).
Solubility in water:	Freely soluble.
Partition coefficient (n-octanol/water):	Not available.
Auto-ignition temperature:	Not available.
Decomposition temperature:	Not available.
Viscosity:	Not available.
Explosive properties:	Not available.
Oxidising properties:	Not available.

### 9.2 Other information

Not available.

## SECTION 10: STABILITY AND REACTIVITY

### 10.1 Reactivity

Not available.

### 10.2 Chemical stability

No hazardous decomposition products will be formed under normal storage and use conditions.

### 10.3 Possibility of hazardous reactions

Not available.

### 10.4 Conditions to avoid

Not available.

### 10.5 Incompatible materials

Strong oxidising agents.

### 10.6 Hazardous decomposition products

Hydrogen chloride gas, Nitrogen oxides Carbon monoxide, Carbon dioxide.  
In case of fire, see section 5.

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### SECTION 11: TOXICOLOGICAL INFORMATION

#### 11.1 Information on toxicological effects

Acute toxicity:	Dermal LD50 (rabbit): > 500 mg/kg Inhalation LC50 (rat) (1h): 3080 mg/kg Oral LD50 (mouse): > 5 g/kg Oral LD 50 (rat): > 10g/kg
Skin corrosion/irritation:	Based on available data, the classification criteria are not met.
Serious eye damage/irritation:	Causes serious eye irritation.
Respiratory/skin sensitisation:	May cause an allergic skin reaction.
Germ cell mutagenicity:	Based on available data, the classification criteria are not met. In vivo and in vitro studies were negative in a related material.
Carcinogenicity:	Due to lack of data the classification is not possible. This product is not considered to be a carcinogen by IARC, ACGIH, NTP, or OSHA.
Reproductive toxicity:	Based on available data, the classification criteria are not met. In animal studies, a related material did not cause birth defects or adverse developmental effects.
Summary of evaluation of the CMR properties:	Not available.
STOT-single exposure:	Due to lack of data the classification is not possible.
STOT-repeated exposure:	Due to lack of data the classification is not possible.
Aspiration Hazard:	Based on available data, the classification criteria are not met.
Other:	Target organs: ears, kidneys.

#### 11.2 Additional information on potential adverse human health effects and symptoms

Eye contact:	Causes serious eye irritation.
Skin contact:	May cause an allergic skin reaction.
Inhalation:	Material may be irritating to mucous membranes and upper respiratory tract. May be harmful if inhaled.
Ingestion:	May be harmful if swallowed.
Aspiration:	Not available.

### SECTION 12: ECOLOGICAL INFORMATION

#### 12.1 Toxicity

Not available.

#### 12.2 Persistence and degradability

Not available.

#### 12.3 Bioaccumulative potential

Not available.

#### 12.4 Mobility in soil

Not available.

#### 12.5 Results of PBT and vPvB assessment

Not available.

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### 12.6 Other adverse effects

Not available.

## SECTION 13: DISPOSAL CONSIDERATIONS

### 13.1 Waste treatment methods

Waste disposal recommendations: Dispose of in a safe manner in accordance with local / national regulations. Have contaminated material treated by a recognized waste processor.

## SECTION 14: TRANSPORT INFORMATION

### Transport information according to ADR/RID/IMDG/ICAO/IATA

#### 14.1 UN Number

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

#### 14.2 UN proper shipping name

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

#### 14.3 Transport hazard class(es)

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

#### 14.4 Packing group

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : Not classified.

#### 14.5 Environmental hazards

ADR/ RID(Land),IMDG(Sea),  
IATA/ICAO (Air) : None.

#### 14.6 Special precautions for user

Not available.

#### 14.7 Transport in bulk according to annex II of Marpol and the IBC Code

Not available.

#### 14.8 Additional transport information

This substance is considered to be non-hazardous for transport.  
Permissible transit condition: Below 25 °C, within 15 days.

## SECTION 15: REGULATORY INFORMATION

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

Hazard symbol:



Risk phrases:

R43 May cause sensitization by skin contact.

Safety phrases:

S36/37 Wear suitable protective clothing and gloves.

### 15.2 Chemical safety assessment

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A chemical safety assessment has not been carried out.

### SECTION 16: OTHER INFORMATION

#### 16.1 Changes since the previous version

Not applicable.

#### 16.2 Abbreviations and acronyms used

ADR:	European Agreement concerning the International Carriage of Dangerous Goods by Road
CAS:	Chemical Abstracts Service (division of the American Chemical Society)
EC (number):	European Community (number)
IATA:	International Air Transport Association
ICAO:	International Civil Aviation Organization
IMDG:	International Maritime Code for Dangerous Goods
IUPAC:	International Union of Pure and Applied Chemistry
PBT:	Persistent, Bioaccumulative and Toxic substance
RID:	Regulations Concerning the International Transport of Dangerous Goods by Rail
STOT:	Specific Target Organ Toxicity
UN (number):	United Nations (number)
vPvB:	very Persistent and very Bioaccumulative

#### 16.3 Key literature references/sources for data

European Chemicals Agency.  
<https://www.echa.europa.eu/web/guest/information-on-chemicals/cl-inventory-database/>

#### 16.4 Method of classification in case of mixture

Not applicable.

#### 16.5 Relevant Hazard statements and/or precautionary statements

For information on hazard and/or precautionary statements refer to section 2 up to and including section 15.

#### 16.6 Training advisement

Not available

#### 16.7 Notice for user(s)

The information provided in this MSDS has been established in accordance with Commission Regulation (EU) 2015/830 of 28 May 2015, amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council, on the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), establishing the European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94, as well as Council Directive 76/769/EEC and Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC of the Commission.

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#### 16.8 Department issuing MSDS



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