


SECTION 1: PRODUCT IDENTIFICATION

| | |
|----------------------------|--|
| PRODUCT NAME | VANCOMYCIN HYDROCHLORIDE, USP |
| PRODUCT CODE | 0274 |
| SUPPLIER | MEDISCA Inc. Tel.: 1.800.932.1039 Fax.: 1.855.850.5855 626 Tom Miller Road, Plattsburgh, NY, 12901 MEDISCA Pharmaceutique Inc. Tel.: 1.800.665.6334 Fax.: 514.338.1693 4509 Rue Dobrin, St. Laurent, QC, H4R 2L8 MEDISCA Australia PTY LTD Tel.: 1.300.786.392 Fax.: 61.2.9700.9047 Unit 7, Heritage Business Park 5-9 Ricketty Street, Mascot, NSW 2020 |
| EMERGENCY PHONE | CHEMTREC Day or Night Within USA and Canada: 1-800-424-9300 NSW Poisons Information Centre: 131 126 National Chemical Emergency Centre 44(0)1235239670 |
| RECOMMENDED USES | Pharmaceutical Manufacturing |
| RESTRICTIONS ON USE | Not applicable |

SECTION 2: HAZARDS IDENTIFICATION

| | |
|---|---|
| GHS CLASSIFICATION | Eye Irritation (Category 2A) Sensitization - Skin (Category 1) Toxic to Reproduction (Category 2) |
| PICTOGRAM |  |
| SIGNAL WORD | Warning |
| HAZARD STATEMENT(S) | Causes serious eye irritation. Suspected of damaging fertility or the unborn child May cause an allergic skin reaction. May cause allergy or asthma symptoms or breathing difficulties Repeated exposure may cause skin dryness or cracking. |
| ADVERSE PHYSIOCHEMICAL, HUMAN HEALTH AND ENVIRONMENTAL EFFECTS | |
| PRECAUTIONARY STATEMENT(S) | Prevention Wear protective gloves, protective clothing, eye and face protection and hearing protection. Wash hands thoroughly after handling. Do not touch eyes. Avoid breathing dust, fume, gas, mist, vapors, and spray. Contaminated work clothing should not be allowed out of the workplace. Obtain, read and follow all special instructions before use. Do not handle until all safety precautions have been read and understood. |

Response IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical help.
 IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical help advice/attention. Take off contaminated clothing and wash it before reuse.
 IF EXPOSED OR CONCERNED: Get medical advice.
 IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms call a poison center or medical professional.

Storage Store locked up.

Disposal Dispose of contents and/or container in accordance with local regulations.

HMIS CLASSIFICATION

Health Hazard 2

Flammability 0

Reactivity 0

Personal Protection E

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS
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.

BOTANICAL NAME

Not applicable

SYNONYM

Vancomycin, monohydrochloride

CHEMICAL FORMULA

C₆₆H₇₅Cl₂N₉O₂₄·HCl

CHEMICAL FAMILY

Tricyclic glycopeptide

CAS NUMBER

1404-93-9

ALTERNATE CAS NUMBER

1404-90-6

MOLECULAR WEIGHT

1485.723

COMPOSITION

| CHEMICAL NAME | CAS NUMBER | EC NUMBER | % BY WEIGHT |
|----------------|------------|-----------|-------------|
| VANCOMYCIN HCl | 1404-93-9 | 604-193-8 | 100 |

There are no additional ingredients present which, within the current knowledge of the supplier and in the concentrations applicable, are classified as health hazards and hence require reporting in this section.

SECTION 4: FIRST-AID MEASURES
IN CASE OF EYE CONTACT

Flush with copious amounts of water for 15 minutes, separating eyelids with fingers. If irritation persists seek medical aid.

IN CASE OF SKIN CONTACT

Wash with soap & water for 15 minutes. If irritation persists seek medical aid.

IF SWALLOWED

Call a physician. Wash out mouth with water. Do not induce vomiting without medical advice.

IF INHALED

Remove to fresh air. If not breathing, give artificial respiration. If breathing is difficult, give oxygen. Call a physician

MEDICAL ATTENTION AND SPECIAL TREATMENT

Get emergency medical help.

SYMPTOMS CAUSED BY EXPOSURE

Not expected to present a significant hazard under anticipated conditions of normal use.

SECTION 5: FIREFIGHTING MEASURES
SPECIFIC HAZARDS ARISING FROM THE CHEMICAL

Not applicable

FLAMMABLE PROPERTIES

May be combustible at high temperature

HAZARDOUS COMBUSTION PRODUCTS

Under fire conditions, hazardous fumes will be present.

SUITABLE & UNSUITABLE EXTINGUISHING MEDIA

Small fire: dry chemical, CO₂ or water spray. **Large fire:** dry chemical, CO₂, alcohol resistant foam or water spray. Do not get water inside containers.

PROTECTIVE EQUIPMENT AND PRECAUTIONS FOR FIREFIGHTERS

Wear self-contained breathing apparatus and protective clothing to prevent contact with skin and eyes.

SECTION 6: ACCIDENTAL RELEASE MEASURES
PERSONAL PRECAUTIONS

Wear respiratory protection. Avoid dust formation. Avoid breathing vapours, mist or gas. Ensure adequate ventilation. Evacuate personnel to safe areas. Avoid breathing dust.

METHODS & MATERIAL FOR CONTAINMENT

On land, sweep or shovel into suitable containers. Minimize generation of dust.

CLEANUP PROCEDURE

Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Wear respirator, chemical safety goggles, rubber boots and heavy rubber gloves. Stop leak if you can do it without risk. Prevent entry into waterways, sewers, basements or confined areas. Shut off all sources of ignition. Evacuate the area. If necessary, employ water fog to disperse the vapors. Absorb the matter with compatible vermiculite or other absorbing material. Place in a suitable container and retain for disposal. Ventilate and clean the affected area. Do not flush into sewerage system or to drains.

REFERENCE TO OTHER SECTIONS

See Section 7 for information on safe handling. See Section 8 for information on personal protection equipment. See Section 13 for disposal information.

SECTION 7: HANDLING AND STORAGE
PRECAUTIONS FOR SAFE HANDLING

Do not inhale. Avoid contact with eyes, skin and clothing. Avoid prolonged or repeated exposure. Wash thoroughly after handling. Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

CONDITIONS FOR SAFE STORAGE

Store away from incompatible materials, in a well-ventilated area. Eliminate all sources of ignition. Store in accordance with local regulations. Do not store in unlabeled containers. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Use appropriate containment to avoid environmental contamination.

STORAGE CONDITIONS

Store in original container, tightly sealed, protected from direct sunlight and moisture. Store at 2°-8°C, short term excursions such as during shipping, up to 25°C are acceptable.

SECTION 8: EXPOSURE CONTROLS/ PERSONAL PROTECTION

Chemical Name: VANCOMYCIN HCl CAS #: 1404-93-9

| | Country | Limit value-8 hours | | Limit value-Short Term | | IDLH | REL | Advisory | Notes |
|------|---------|---------------------|-------------------|------------------------|-------------------|------|-----|----------|-------|
| | | ppm | mg/m ³ | ppm | mg/m ³ | | | | |
| OSHA | USA | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |

| | | | | | | | | | |
|---------------|-------------|-----|-----|-----|-----|-----|-----|-----|-----|
| ACGIH | USA | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| NIOSH | USA | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| WEEL | USA | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| HSIS | Australia | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| HSE | UK | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |
| GESTIS | Add Country | N/L | N/L | N/L | N/L | N/L | N/L | N/A | N/A |

N/L = Not listed ; N/A = Not Available

PELs are 8-hour TWAs = Limit value - Eight hours

Ceiling or Short-Term TWA = STEL = Limit value - Short term

EXPOSURE GUIDELINES

Consult local authorities for provincial or state exposure limits. Particulates not otherwise regulated, respirable fraction: 5 mg/m³

PERSONAL PROTECTIVE EQUIPMENT

Eyes: Wear appropriate protective eyeglasses or chemical safety goggles as described by WHMIS or OSHA's eye and face protection regulations in 29 CFR 1910.133 or European Standard EN166. **Skin:** Wear appropriate gloves to prevent skin exposure. **Clothing:** Wear appropriate protective clothing to minimize contact with skin. **Respirators:** Follow WHMIS or OSHA respirator regulations found in 29 CFR 1910.134 or European Standard EN 149. Use a NIOSH/MSHA or European Standard EN 149 approved respirator if exposure limits are exceeded or if irritation or other symptoms are experienced. **Thermal Hazards:** For products representing a thermal hazard, appropriate Personal Protective Equipment should be used.

SPECIFIC ENGINEERING CONTROLS

Adequate mechanical ventilation. Fumehood, eye wash station, and safety shower.

BIOLOGICAL MONITORING

Not available

CONTROL BANDING

Not available

NOTES

USP: ELV: Industrial Use: TWA: 100 micrograms/m³

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES
PHYSICAL STATE

Solid

DESCRIPTION

White, almost white, or tan to brown, free-flowing powder, odorless. Is hygroscopic.

SOLUBILITY

Freely soluble in water; insoluble in ether and in chloroform.

ODOR

Odorless

FLAMMABILITY

May be combustible at high temperature

AUTO-IGNITION TEMPERATURE

Not available

BOILING POINT

Not available

DECOMPOSITION TEMPERATURE

Not available

EVAPORATION RATE

Not available

EXPLOSIVE LIMIT

Not available

FLASH POINT

Not available

log P (OCTANOL-WATER)

Not available

LOWER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

MELTING/FREEZING POINT

Not available

PARTICLE CHARACTERISTICS

Not available

OXIDIZING PROPERTY

Not available

pH

2.5 - 4.5 (5%)

RELATIVE DENSITY (WATER = 1)

Not available

SPECIFIC GRAVITY

Not available

UPPER FLAMMABLE/EXPLOSIVE LIMIT(S)

Not available

**VAPOR DENSITY
(AIR = 1)**

Not available

VAPOR PRESSURE

Not available

VISCOSITY

Not available

The physical data presented above are typical values and should not be construed as a specification.

SECTION 10: STABILITY AND REACTIVITY

REACTIVITY

Not established

CHEMICAL STABILITY

Stable under recommended storage conditions

INCOMPATIBLE MATERIALS

Strong oxidants, alkaline preparations.

**HAZARDOUS DECOMPOSITION
PRODUCTS**

Toxic fumes of carbon monoxide, carbon dioxide, nitrogen oxides, hydrogen chloride and other gases may occur

HAZARDOUS POLYMERIZATION

Will not occur

**POSSIBILITY OF HAZARDOUS
REACTION**

Not established

CONDITIONS TO AVOID

Moisture, sunlight and extreme temperatures

SECTION 11: TOXICOLOGICAL INFORMATION

ACUTE TOXICITY

 Oral: Rat: LD50: (mg/kg): > 10 000
 Dermal: Rabbit LD50: (mg/kg): > 500
 Inhalation: Rat: LC50: (mg/L/4hr): Not available

SKIN CORROSION/IRRITATION

 Based on available data, the classification criteria are not met.
 Rabbit: Skin: Irritation test; Result: Not irritating; Organ: Skin.

**SERIOUS EYE DAMAGE/EYE
IRRITATION**

 Causes serious eye irritation: pH 2.5 - 4.5 (5%)
 Rabbit: Eye: Irritation test; Result: Irritant; Severity: Moderate

RESPIRATORY SENSITIZATION

May cause allergy or asthma symptoms or breathing difficulties if inhaled.

SKIN SENSITIZATION

May cause an allergic skin reaction. Dermal hypersensitivity reactions with therapeutic use have been reported.

GERM CELL MUTAGENICITY

Based on available data, the classification criteria are not met.

CARCINOGENICITY
OSHA VANCOMYCIN HYDROCHLORIDE is not listed.

NTP VANCOMYCIN HYDROCHLORIDE is not listed.

IARC VANCOMYCIN HYDROCHLORIDE is not evaluated.

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

**ADDITIONAL CARCINOGENICITY
INFORMATION**

Due to lack of data the classification is not possible.

REPRODUCTIVE TOXICITY

 Suspected of damaging fertility or the unborn child.
 Intravenous: Rat (6-15 days pregnant): 2000 mg/kg: decreased fertility and fetal death.
 Intravenous: Rabbit (6-18 days pregnant): 1560 mg/kg: decreased fertility and fetotoxicity.

**SPECIFIC TARGET ORGAN TOXICITY -
SINGLE EXPOSURE**

Due to lack of data the classification is not possible.

**SPECIFIC TARGET ORGAN TOXICITY -
REPEATED EXPOSURE**

Due to lack of data the classification is not possible.

| | |
|---------------------------------------|--|
| ASPIRATION HAZARDS | Due to lack of data the classification is not possible. |
| SIGNS AND SYMPTOMS OF EXPOSURE | <p>ROUTES OF EXPOSURE: Oral, Dermal</p> <p>EARLY ONSET SYMPTOMS RELATED TO EXPOSURE: Not available</p> <p>DELAYED HEALTH EFFECT FROM EXPOSURE: Superinfections. Ototoxicity. Kidney failure.</p> <p>Symptoms related to the physical, chemical, and toxicological characteristics Bitter or metallic taste. Gastrointestinal disturbances. Skin rash. Skin redness. Itching. Chest pain. Back pain. Fainting. Fast heartbeat. Chills. Cough. Fever. Sore throat. Difficulty breathing. Change in frequency or amount of urination. Drowsiness. Weakness. Thirst. Loss of appetite. Hearing problems. Diarrhea. Black or bloody stools.</p> <p>Medical conditions aggravated by exposure Hearing disorders (active or history of). Inflammatory bowel disease. Intestinal obstruction. Impaired kidney function.</p> |
| POTENTIAL HEALTH EFFECTS | <p>Inhalation May be harmful if inhaled. May cause respiratory tract irritation. May cause allergy or asthma symptoms or breathing difficulties if inhaled.</p> <p>Ingestion May be harmful if swallowed.</p> <p>Skin May be harmful if absorbed through skin. Causes skin irritation. May cause an allergic skin reaction.</p> <p>Eyes Causes serious eye irritation.</p> |

SECTION 12: ECOLOGICAL INFORMATION

| | |
|--------------------------------------|--|
| ECOTOXICITY | <p>EC50: 48 Hr: Crustacea: (mg/L): Not available LC50: 96 Hr: Fish: (mg/L): Not available EC50: 72 or 96 Hr: Algae (or other aqua plants): (mg/L): Not available</p> |
| PERSISTENCE AND DEGRADABILITY | Not available |
| BIOACCUMULATIVE POTENTIAL | Not available |
| MOBILITY IN SOIL | Freely soluble in water. |
| OTHER ADVERSE EFFECTS | <p>Not available</p> <p>This product is not intended to be released into the environment</p> |

SECTION 13: DISPOSAL CONSIDERATIONS

| | |
|-------------------------|---|
| DISPOSAL METHODS | Dispose of in accordance with federal / local laws and regulations. Avoid release into the environment. |
|-------------------------|---|

SECTION 14: TRANSPORT INFORMATION

| | |
|--------------------------------|--------------------|
| UN PROPER SHIPPING NAME | Not dangerous good |
| UN NUMBER | Not applicable |
| CLASS | Not applicable |
| PACKING GROUP | Not applicable |

AUSTRALIA

HAZCHEM Not Applicable

**EU
TRANSPORT IN BULK ACCORDING TO
ANNEX II OF MARPOL 73/78 AND THE
IBC CODE** Not listed

ENVIRONMENTAL HAZARDS Not available

SPECIAL SHIPPING INFORMATION Not applicable

SECTION 15: REGULATORY INFORMATION

UNITED STATES REGULATIONS

| Chemical Name & CAS | CERCLA 40 CFR Part 302.4 | SARA (Title III) 40 CFR Part 372.65 | EPA 40 CFR Part 355 | | Pennsylvania | Right-to-know | | California Prop 65 |
|---------------------------|--------------------------------|---|---------------------|------------|--------------|---------------|---------------|-----------------------|
| | | | Appendix A | Appendix B | | New Jersey | Massachusetts | |
| VANCOMYCIN HCl, 1404-93-9 | N/L | N/L | N/L | N/L | N/L | N/L | N/L | N/L |

N/L = Not Listed; X = Listed

AUSTRALIAN REGULATIONS

| Chemical Name & CAS | Poisons and Therapeutic Goods | Therapeutic Goods Act | Code of Practices - Illicit Drug Precursors | Poisons Standard | Work Health and Safety Regulations | Inventory of Industrial Chemicals |
|---------------------------|-------------------------------------|--------------------------|---|------------------|--|---|
| VANCOMYCIN HCl, 1404-93-9 | N/L | *Listed as Schedule 4 | N/L | Listed | N/L | N/L |

N/L = Not Listed

EU REGULATIONS

| Chemical Name & CAS | REACH ANNEX XVII | REACH ANNEX XIV | EC 1005/2009 | EC 850/2004 | EC 1107/2009 | PIC - Prior Informed Consent Regulation | EC 2012/18 |
|---------------------------|------------------------|-----------------------|-----------------|----------------|-----------------|---|---------------|
| VANCOMYCIN HCl, 1404-93-9 | N/L | N/L | N/L | N/L | N/L | N/L | N/L |

N/L = Not Listed; X = Listed

Any EU regulation not listed above is not applicable to this product.

**SUBJECT TO INTERNATIONAL
AGREEMENT** Not applicable

NOTES *Listed as the base.

SECTION 16: OTHER INFORMATION

REFERENCES Available upon request

ABBREVIATIONS AND ACRONYMS

ACGIH - American Conference of Governmental Industrial Hygienists; **AIHA WEEL** – American Industrial Hygiene Association Workplace Environment Exposure Levels; **CAESAR** – Computer Assisted Evaluation of industrial chemical Substances According to Regulations; **CAS** – Chemical Abstract Service; **CERCLA** – Comprehensive Environmental Response, Compensation, and Liability Act; **EC50** – Effective Concentration, 50%; **EPA** – Environmental Protection Agency; **GHS** – Global Harmonized System; **HMIS** – Hazardous Materials Information System; **HSE** – Health and Safety Executive; **HSIS** – Hazardous Substances Information System; **IARC** – International Agency for Research on Cancer; **IDLH** - Immediately Dangerous to Life or Health; **IRFMN** – Ready Biodegradability Model; **ISS** – Istituto Superiore Sanità; **LC50** – Lethal Concentration, 50%; **LD50** – Lethal Dose, 50%; **MSHA** - Mine Safety and Health Administration; **NIOSH** – National Institute for Occupational Safety and Health; **NTP** – National Toxicology Program; **OSHA PEL** – Occupational Safety & Health Administration Permissible Exposure Limits; **QSAR** – Quantitative Structure-activity relationship; **REL** - Recommended Exposure Limit; **SARA** – Superfund Amendments and Reauthorization Act; **STEL** – Short Term Exposure Limit; **TLV** – Threshold Limit Value; **TWA** – Time Weighted Average; **WHMIS** – Workplace Hazardous Materials Information System

LAST REVISION

04/2025

SUPERSEDES

01/2023

For a list of changes to the SDS since the last version, please communicate with MEDISCA at www.medisca.com

DISCLAIMER

This document was created in accordance with OSHA, Safe Work Australia and WHMIS regulations. The above information is believed to be correct but does not purport to be all inclusive and shall be used only as a guide. The information in this document is based on the present state of our knowledge and is applicable to the product with regard to appropriate safety precautions. It does not represent any guarantee of the properties of the product. MEDISCA® shall not be held liable for any damage resulting from handling or from contact with the above product. Recipients of the product must take responsibility for observing existing laws and regulations.

SUPPLEMENTARY INFORMATION

For all country specific requirements not outlined on this Safety Data Sheet, please request Supplementary Page to this Safety Data Sheet.