MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address
Hospira Inc.  
275 North Field Drive  
Lake Forest, Illinois USA  
60045

Emergency Telephone
CHEMTREC: North America: 800-424-9300;  
International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418

Hospira, Inc., Non-Emergency  
224-212-2000

Product Name
Vancomycin Hydrochloride for Injection, USP

Synonyms
VANCOMYCIN HYDROCHLORIDE - vancomycin hydrochloride injection, powder, lyophilized, for solution

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Vancomycin Hydrochloride

Chemical Formula
C_{66}H_{75}Cl_{2}N_{9}O_{24}• HCl

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

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vancomycin Hydrochloride</td>
<td>100</td>
<td>1404-93-9</td>
<td>YW4380000</td>
</tr>
</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

<table>
<thead>
<tr>
<th>Substance</th>
<th>IARC</th>
<th>NTP</th>
<th>OSHA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vancomycin Hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview
Sterile Vancomycin Hydrochloride is a powder containing vancomycin hydrochloride, a purified tricyclic glycopeptide antibiotic derived from Amycolatopsis orientalis (formerly Nocardia orientalis). Clinically, it is used to treat potentially, life-threatening infections. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract, and a potential contact sensitizer which may induce allergic skin reactions. Based on clinical use, possible target organs include the auditory system, the hematopoietic system, and the kidneys.

Occupational Exposure Potential
Information on the absorption of this product via inhalation or skin contact is not available. Avoid dust or liquid aerosol generation and skin contact.

Signs and Symptoms
None known from occupational exposure. In clinical use, vancomycin hydrochloride has produced ototoxicity (deafness), renal injury, a drop in blood pressure (following intravenous administration), lowered leukocyte or eosinophil counts in the blood, and allergic reactions such as urticaria, rashes, nausea, chills, fever and even anaphylactic responses.
Product Name: Vancomycin Hydrochloride for Injection, USP

Medical Conditions Aggravated by Exposure

Pre-existing hypersensitivity to vancomycin or related antibiotics; pre-existing auditory, renal, or hematopoietic ailments.

4. FIRST AID MEASURES

Eye contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin contact
Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Inhalation
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Ingestion
Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability
Non-flammable powder. However, powder may be ignitable under high temperature.

Fire & Explosion Hazard
None anticipated. As with all powders, minimize the creation of dusty environments.

Extinguishing media
As with any fire, use extinguishing media appropriate for primary cause of fire.

Special Fire Fighting Procedures
No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal
For spilled powder, isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill 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.

7. HANDLING AND STORAGE

Handling
No special handling required under conditions of normal product use.

Storage
No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Special Precautions
No special precautions are required for hazard control. Employees with known allergies to vancomycin hydrochloride or related antibiotics should consult a
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Component</td>
<td>mg/m3</td>
</tr>
<tr>
<td>Vancomycin Hydrochloride</td>
<td>Not Applicable</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Respiratory protection

Respiratory protection is normally not needed during intended product use. However, if the generation of dusts or aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne dust or aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air-purifying respirator or supplied air. A respiratory protection program that meets OSHA’s 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.

Skin protection

If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

Eye protection

Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended.

Engineering Controls

Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Appearance/Physical State</td>
<td>Solid</td>
</tr>
<tr>
<td>Color</td>
<td>Off-white to white to tan lyophilized powder</td>
</tr>
<tr>
<td>Odor</td>
<td>NA</td>
</tr>
<tr>
<td>Odor Threshold:</td>
<td>NA</td>
</tr>
<tr>
<td>pH</td>
<td>4.0 (2.5 to 4.5) when reconstituted</td>
</tr>
<tr>
<td>Melting point/Freezing point</td>
<td>NA</td>
</tr>
<tr>
<td>Initial Boiling Point/Boiling Point Range:</td>
<td>NA</td>
</tr>
<tr>
<td>Evaporation Rate:</td>
<td>NA</td>
</tr>
<tr>
<td>Flammability (solid, gas):</td>
<td>NA</td>
</tr>
<tr>
<td>Upper/Lower Flammability or Explosive Limits:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Pressure:</td>
<td>NA</td>
</tr>
<tr>
<td>Vapor Density:</td>
<td>NA</td>
</tr>
<tr>
<td>Specific Gravity:</td>
<td>NA</td>
</tr>
<tr>
<td>Solubility:</td>
<td>Freely soluble in water; slightly soluble in alcohol.</td>
</tr>
<tr>
<td>Partition coefficient: n-octanol/water:</td>
<td>NA</td>
</tr>
<tr>
<td>Auto-ignition temperature:</td>
<td>NA</td>
</tr>
<tr>
<td>Decomposition temperature:</td>
<td>NA</td>
</tr>
</tbody>
</table>
10. STABILITY AND REACTIVITY

Reactivity
Not determined.

Chemical Stability
Stable under standard use and storage conditions.

Hazardous Reactions
Not determined

Conditions to avoid
Not determined

Incompatibilities
Not determined

Hazardous decomposition products
Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), or hydrogen chloride (HCl).

Hazardous Polymerization
Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity
Not determined for the product formulation. Information for the ingredients is as follows:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>*Vancomycin Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>&gt;5000</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td>*Vancomycin Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Dermal</td>
<td>&gt;500</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
<tr>
<td>*Vancomycin Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>251-312</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>292</td>
<td>mg/kg</td>
<td>Dog</td>
</tr>
<tr>
<td>*Vancomycin Hydrochloride</td>
<td>100</td>
<td>LC50(1h)</td>
<td>Inhalation</td>
<td>3080</td>
<td>mg/m^3</td>
<td>Rat</td>
</tr>
<tr>
<td>Vancomycin</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>319</td>
<td>mg/kg</td>
<td>Rat</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>430,489</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td>Vancomycin</td>
<td>100</td>
<td>LD50</td>
<td>Intraperitoneal</td>
<td>2218</td>
<td>mg/kg</td>
<td>Rat</td>
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<tr>
<td></td>
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<td></td>
<td>1734</td>
<td>mg/kg</td>
<td>Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>737</td>
<td>mg/kg</td>
<td>Guinea Pig</td>
</tr>
</tbody>
</table>

Aspiration Hazard
None anticipated from normal handling of the intact product.

Dermal Irritation/Corrosion
None anticipated from normal handling of the intact product.

Ocular Irritation/Corrosion
None anticipated from normal handling of the intact product. However, inadvertent contact of this product formulation with eyes may produce irritation with redness and discomfort.

Dermal or Respiratory Sensitization
None anticipated from normal handling of the intact product. However, in clinical use, intravenous administration has resulted in “red-man” syndrome, a condition characterized by erythema, flushing, or rash over the face and upper torso, and sometimes by hypotension and shock-like symptoms. The effect appears to be due in part to the release of histamine and is usually related to rapid infusion. In addition, hypersensitivity reactions occur in about 5% of patients and may include rashes, fever, chills, and rarely, anaphylactoid reactions, exfoliative dermatitis, Stevens-Johnson syndrome, toxic epidermal necrolysis, and vasculitis.
Product Name: Vancomycin Hydrochloride for Injection, USP

Reproductive Effects
Developmental toxicology studies in rats and rabbits were performed at dosages up to 200 and 120 mg/kg/day, respectively. No developmental toxicity was observed in the rat even in the presence of maternal toxicity. In the rabbit, reduction in fetal weight was noted at the highest dose, which was higher than the dose (80 mg/kg) that produced maternal toxicity.

Mutagenicity
*Vancomycin hydrochloride was not mutagenic in bacterial or mammalian cells. *Lilly MSDS

Carcinogenicity
Long-term carcinogenicity studies in animals have not been conducted with vancomycin hydrochloride.

Target Organ Effects
Based on clinical use, possible target organs include the auditory system, the hematopoietic system, and the kidneys.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity
Not determined for product.

Persistence/Biodegradability
Not determined for product.

Bioaccumulation
Not determined for product.

Mobility in Soil
Not determined for product.

13. DISPOSAL CONSIDERATIONS

Waste Disposal
All waste materials must be properly characterized. Disposal should be performed in accordance with federal, state or local regulatory requirements.

Container Handling and Disposal
Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS: Not regulated

IMDG STATUS: Not regulated

ICAO/IATA STATUS: Not regulated

Transport Comments: None
15. REGULATORY INFORMATION

### USA Regulations

<table>
<thead>
<tr>
<th>Substance</th>
<th>TSCA Status</th>
<th>CERCLA Status</th>
<th>SARA 302 Status</th>
<th>SARA 313 Status</th>
<th>PROP 65 Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vancomycin Hydrochloride</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

**RCRA Status**
- Not Listed

**U.S. OSHA Classification**
- Possible Sensitizer
- Possible Target Organ Toxin
- Possible Irritant

**GHS Classification**
*In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

**Hazard Class**
- Not Applicable

**Hazard Category**
- Not Applicable

**Signal Word**
- Not Applicable

**Symbol**
- Not Applicable

**Prevention**
- P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

**Hazard Statement**
- Not Applicable

**Response:**
- IF INHALED: If breathing is difficult, remove to fresh air and keep at rest in a position comfortable for breathing. If experiencing respiratory symptoms call a POISON CENTER or doctor/physician.

- IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs, seek medical advice/attention. Wash contaminated clothing before reuse.

- 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 attention. Get medical attention if you feel unwell.

**EU Classification**
*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Vancomycin Hydrochloride.

**Classification(s):**
- Not Applicable

**Symbol:**
- Not Applicable

**Indication of Danger:**
- Not Applicable

**Risk Phrases:**
- Not Applicable

**Safety Phrases:**
- S23 - Do not breathe vapor.
- S24 - Avoid contact with skin.
- S25 - Avoid contact with eyes.
- S37/39 - Wear suitable gloves and eye/face protection.
### 16. OTHER INFORMATION:

**Notes:**
- ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value
- CAS: Chemical Abstracts Service Number
- CERCLA: US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
- DOT: US Department of Transportation Regulations
- EEL: Employee Exposure Limit
- IATA: International Air Transport Association
- LD50: Dosage producing 50% mortality
- NA: Not applicable/Not available
- NE: Not established
- NIOSH: National Institute for Occupational Safety and Health
- OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
- Prop 65: California Proposition 65
- RCRA: US EPA, Resource Conservation and Recovery Act
- RTECS: Registry of Toxic Effects of Chemical Substances
- SARA: Superfund Amendments and Reauthorization Act
- STEL: 15-minute Short Term Exposure Limit
- TSCA: Toxic Substance Control Act
- TWA: 8-hour Time Weighted Average

**MSDS Coordinator:** Hospira GEHS  
**Date Prepared:** Thu. 03/29/2012  
**Obsolete Date:** 11/03/2011

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