SAFETY DATA SHEET

Product Name: Sterile Vancomycin Hydrochloride

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

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

Emergency Telephone #’s
CHEMTREC: North America: 800-424-9300; International 1-703-527-3887;
224 212-2055

Product Name
Sterile Vancomycin Hydrochloride

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

2. HAZARD INFORMATION

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.

Medical Conditions Aggravated by Exposure
Pre-existing hypersensitivity to vancomycin or related antibiotics; pre-existing auditory, renal, or hematopoietic ailments.

Carcinogen Lists:
IARC: Not listed
NTP: Not listed
OSHA: Not listed

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name: Vancomycin Hydrochloride
Chemical Formula: C₆₆H₇₅Cl₂N₉O₂₄• HCl

<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>

May contain hydrochloric acid and/or sodium hydroxide for pH adjustment.
Product Name: Sterile Vancomycin Hydrochloride

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 fire fighting 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 temperature and/or light 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 health and/or safety professional prior to working with open containers of this material.
8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>OSHA-PEL</th>
<th>ACGIH-TLV</th>
<th>Hospira EEL</th>
<th>Other Limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vancomycin Hydrochloride</td>
<td>8 hr TWA: Not Established</td>
<td>8 hr TWA: Not Established</td>
<td>8 hr TWA: Not Established</td>
<td>Not Established</td>
</tr>
</tbody>
</table>

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
EEL: Employee Exposure Limit.
TWA: 8 hour Time Weighted Average.
STEL: 15-minute Short Term Exposure Limit.

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

Appearance/Physical State: Off-white to white to tan lyophilized powder
Odor: NA
Odor Threshold: NA
pH: When reconstituted, forms a clear solution in water with a pH of 4.0 (2.5 to 4.5).
Melting point/Freezing point: NA
Initial Boiling Point/Boiling Point Range: NA
Evaporation Rate: NA
Flammability (solid, gas): NA
Upper/Lower Flammability or Explosive Limits: NA
Vapor Pressure: NA
Vapor Density (Air =1): NA
Evaporation Rate: NA
Specific Gravity: NA
Solubility: Freely soluble in water; slightly soluble in alcohol.
Log Partition coefficient: n-octanol/water: NA
Auto-ignition temperature: NA
Decomposition temperature: NA
Product Name: Sterile Vancomycin Hydrochloride

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:

<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 mg/kg</td>
<td>Rat</td>
<td></td>
</tr>
<tr>
<td>*Vancomycin Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Dermal</td>
<td>&gt;500 mg/kg</td>
<td>Rabbit</td>
<td></td>
</tr>
<tr>
<td>*Vancomycin Hydrochloride</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>251-312 mg/kg, 292 mg/kg</td>
<td>Rat, Dog</td>
<td></td>
</tr>
<tr>
<td>*Vancomycin Hydrochloride</td>
<td>100</td>
<td>LC50(1h)</td>
<td>Inhalation</td>
<td>3080 mg/m³</td>
<td>Rat</td>
<td></td>
</tr>
<tr>
<td>Vancomycin</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>319 mg/kg, 430,489 mg/kg</td>
<td>Rat, Mouse</td>
<td></td>
</tr>
<tr>
<td>Vancomycin</td>
<td>100</td>
<td>LD50</td>
<td>Intraperitoneal</td>
<td>2218 mg/kg, 1734 mg/kg, 737 mg/kg</td>
<td>Rat, Mouse, Guinea Pig</td>
<td></td>
</tr>
</tbody>
</table>

LD50: Dosage that produces 50% mortality.
*Lilly MSDS

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 “red-man” syndrome, 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.
11. TOXICOLOGICAL INFORMATION: continued

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.

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.

*Lilly MSDS

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

DOT STATUS
Not Regulated

Proper Shipping Name
NA

Hazard Class
NA

UN Number
NA

Packing Group
NA

Reportable Quantity
NA

ICAO/IATA STATUS
Not regulated

Proper Shipping Name
NA

Hazard Class
NA

UN Number
NA

Packing Group
NA

Reportable Quantity
NA

IMDG STATUS
Not regulated

Proper Shipping Name
NA

Hazard Class
NA

UN Number
NA

Packing Group
NA

Reportable Quantity
NA

Notes: DOT - US Department of Transportation Regulations
**Product Name:** Sterile Vancomycin Hydrochloride

### 15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>Regulatory Category</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>U.S. TSCA Status</td>
<td>This product is exempt.</td>
</tr>
<tr>
<td>U.S CERCLA Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>U.S. SARA 302 Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>U.S. SARA 313 Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>U.S. RCRA Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>U.S. PROP 65 (Calif.)</td>
<td>Not listed</td>
</tr>
</tbody>
</table>

Notes:
TSCA, Toxic Substance Control Act;
CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act;
SARA, Superfund Amendments and Reauthorization Act;
Prop 65, California Proposition 65

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

**GHS Classification***

*In the EU, classification under GHS 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.

<table>
<thead>
<tr>
<th>Hazard Class</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard Category</td>
<td>NA</td>
</tr>
<tr>
<td>Symbol</td>
<td>NA</td>
</tr>
<tr>
<td>Signal Word</td>
<td>NA</td>
</tr>
<tr>
<td>Hazard Statement</td>
<td>NA</td>
</tr>
</tbody>
</table>

**Prevention:**
Avoid breathing dust/vapors/spray.
In case of inadequate ventilation wear respiratory protection as specified by the manufacturer/supplier or the competent authority.
Wear protective gloves as specified by the manufacturer/supplier or the competent authority.
Contaminated work clothing should not be allowed out of the workplace.

**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.
Product Name: Sterile Vancomycin Hydrochloride

15. REGULATORY INFORMATION: continued

EU Classifications*: *Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

<table>
<thead>
<tr>
<th>Classification(s)</th>
<th>NA</th>
</tr>
</thead>
<tbody>
<tr>
<td>Symbol</td>
<td>NA</td>
</tr>
<tr>
<td>Indication of Danger</td>
<td>NA</td>
</tr>
<tr>
<td>EU Risk Phrases</td>
<td>S22: Do not breathe dust</td>
</tr>
<tr>
<td></td>
<td>S23: Do not breathe vapor or spray</td>
</tr>
<tr>
<td></td>
<td>S25: Avoid contact with eyes</td>
</tr>
<tr>
<td></td>
<td>S26: In case of contact with eyes, rinse immediately with plenty of water and seek medical advice</td>
</tr>
<tr>
<td></td>
<td>S37/39: Wear suitable gloves and eye/face protection.</td>
</tr>
</tbody>
</table>

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: September 15, 2005
Date(s) Revised October 21, 2008
November 18, 2010

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