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 (02) 8014 4880

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

Product Name
Daptomycin Injection

Synonyms

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Daptomycin

Chemical Formula
C_{72}H_{101}N_{17}O_{26}

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
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</thead>
<tbody>
<tr>
<td>Daptomycin</td>
<td>100</td>
<td>103060-53-3</td>
<td>HB5626000</td>
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</tbody>
</table>

3. HAZARD INFORMATION

Carcinogen List

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

Emergency Overview
Daptomycin Injection is a powder containing daptomycin, a cyclic lipopeptide antibacterial derived from the fermentation of Streptomyces roseosporus. It has a spectrum of antibacterial activity similar to that of vancomycin, but with greater potency in vitro against many bacterial strains. Clinically, it is indicated for the treatment of susceptible bacterial infections. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the eyes, respiratory tract, skeletal muscles, nervous system and liver.

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

Signs and Symptoms
None known from occupational exposures. None anticipated from intact product. In clinical use, adverse reactions may include headache, nausea, vomiting, diarrhea, fungal infections, rash, infusion site reaction, increased creatine phosphokinase (CPK) and abnormal liver enzymes. Additional reactions have included hypersensitivity, manifested as pulmonary eosinophilia, vesicobullous rash with mucous membrane involvement and sensation of
oropharyngeal swelling. In addition, anaphylaxis and infusion reactions, including tachycardia, wheezing, pyrexia, rigors, systemic flushing, vertigo, syncope and metallic taste, have been reported infrequently. Other reported adverse effects include anemia, dyspnea, and musculoskeletal disorders including arthralgia and limb pain, muscle pain, weakness, or neuropathy.

Medical Conditions Aggravated by Exposure
Pre-existing hypersensitivity to daptomycin; pre-existing skeletal muscle, nervous system or liver 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
None anticipated for this product. However, many organic powders will combust at high temperatures.

Fire & Explosion Hazard
None anticipated for this product. Avoid the creation of dusty atmospheres.

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
Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Collect powder using methods that minimize the creation of airborne dusts. If the spill occurs after reconstitution, absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill 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
Product Name: Daptomycin Injection

container label, or the product insert.

Special Precautions  No special precautions are required for hazard control.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

<table>
<thead>
<tr>
<th>Exposure Guidelines</th>
<th>Exposure limits</th>
</tr>
</thead>
<tbody>
<tr>
<td>Component</td>
<td>Type</td>
</tr>
<tr>
<td>Daptomycin</td>
<td>Not Applicable</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

Appearance/Physical State  Solid
Color  light yellow or light brown lyophilized powder
Odor  NA
Odor Threshold:  NA
pH:  4.0 - 5.0 After reconstitution
Melting point/Freezing point:  215oC
Initial Boiling Point/Boiling Point Range:  NA
Evaporation Rate:  NA
Flammability (solid, gas):  NA
Upper/Lower Flammability or Explosive Limits:
Vapor Pressure:  NA
Vapor Density:  NA
Specific Gravity:  NA
Solubility:  Highly soluble (> 1000 mg/mL) in water
Partition coefficient: n-octanol/water:  NA
Auto-ignition temperature:  NA
Decomposition temperature:  NA
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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) and nitrogen oxides (NOx).

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>
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</thead>
<tbody>
<tr>
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<td>100</td>
<td>LD</td>
<td>Oral</td>
<td>&gt; 2000</td>
<td>mg/kg</td>
<td>Not specified</td>
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<tr>
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<td>LD</td>
<td>Dermal</td>
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<td>mg/kg</td>
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<tr>
<td>Daptomycin</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>600</td>
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<td>Mouse</td>
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<td>Rat</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Intravenous</td>
<td>&gt; 200</td>
<td>mg/kg</td>
<td>Dog</td>
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<tr>
<td></td>
<td></td>
<td></td>
<td>Intravenous</td>
<td>between 25 - 200</td>
<td>mg/kg</td>
<td>Monkey</td>
</tr>
</tbody>
</table>

Aspiration Hazard
None anticipated from normal handling of this product.

Dermal Irritation/Corrosion
None anticipated from normal handling of this product. However, daptomycin was slightly irritating in a skin irritation study in rabbits.

Ocular Irritation/Corrosion
None anticipated from normal handling of this product. However, daptomycin was slightly irritating in an eye irritation study in rabbits. Inadvertent contact of this product with eyes may produce irritation and redness.

Dermal or Respiratory Sensitization
None anticipated from normal handling of this product. In clinical use, anaphylaxis and infusion reactions, including tachycardia, wheezing, pyrexia, rigors, systemic flushing, vertigo, syncope and metallic taste, have been reported infrequently.

Reproductive Effects
Daptomycin did not affect the fertility or reproductive performance of male and female rats when given intravenously at dosages up to 150 mg/kg/day. Reproductive and teratology studies performed in rats and rabbits at dosages up to 75 mg/kg showed no evidence of harm to the fetus due to daptomycin.

Mutagenicity
Daptomycin was not mutagenic or clastogenic in a battery of genotoxicity tests, including the Ames assay, a mammalian cell gene mutation assay, a test
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Carcinogenicity

Long-term carcinogenicity studies in animals have not been conducted to evaluate the carcinogenic potential of daptomycin.

Target Organ Effects

Based on clinical use, possible target organs include the eyes, respiratory tract, skeletal muscles, nervous system and liver. In animals, repeated administration of daptomycin has been associated with effects on skeletal muscle without changes in cardiac or smooth muscle. Skeletal muscle effects included degenerative/regenerative changes and variable elevations in CPK. No fibrosis or rhabdomyolysis was evident in repeat-dose studies up to the highest dosage tested in rats (150 mg/kg/day) or dogs (100 mg/kg/day). The degree of skeletal myopathy showed no increase when treatment was extended from 1 month to up to 6 months. Severity was dose-dependent. All muscle effects, including microscopic changes, were fully reversible within 30 days following cessation of dosing. In adult animals, effects on peripheral nerve (characterized by axonal degeneration and frequently accompanied by significant losses of patellar reflex, gag reflex, and pain perception) were noted at dosages higher than those associated with skeletal myopathy. Deficits in the dogs’ patellar reflexes were seen within 2 weeks of the start of treatment at a dosage of 40 mg/kg, with some clinical improvement noted within 2 weeks of the cessation of dosing. However, at a dosage of 75 mg/kg/day for 1 month, 7/8 dogs failed to regain full patellar reflex responses within the duration of a 3-month recovery period. In a separate study in dogs given dosages of 75 and 100 mg/kg/day for 2 weeks, minimal residual histological changes were noted at 6 months after cessation of dosing. However, recovery of peripheral nerve function was evident.

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. Further, disposal should be performed in accordance with the 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
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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>
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<tbody>
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<td>Daptomycin</td>
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<td>Not Listed</td>
<td>Not Listed</td>
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</tr>
</tbody>
</table>

RCRA Status Not Listed
U.S. OSHA Classification Target Organ Toxin

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 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. Wash hands after handling.

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 Daptomycin.

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.
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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: 06/16/2011
Obsolete Date: N/A

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