Product Name: Cisplatin Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

| Manufacturer Name And Address | Hospira Inc.  
275 North Field Drive  
Lake Forest, Illinois USA  
60045 |
|-----------------------------|------------------------------------------------|
| Distributor                | Hospira Healthcare Corporation  
111 Dr. Frederik-Philips, Suite 600  
Saint-Laurent, Québec H4M2X6 |
| 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                | Cisplatin Injection |
| Synonyms                    | Cis-Diamminodichloroplatinum; platinum (II),diaminedichloro-cis-; Platinum diamminodichloride |

2. COMPOSITION/INFORMATION ON INGREDIENTS

<table>
<thead>
<tr>
<th>Active Ingredient Name</th>
<th>Cisplatin</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chemical Formula</td>
<td>H₂N₂PtCl₂</td>
</tr>
<tr>
<td>Preparation</td>
<td>Non-hazardous ingredients include Water for Injection and mannitol. Hazardous ingredients present at less than 1% include sodium chloride. Hydrochloric acid is used to adjust the pH.</td>
</tr>
</tbody>
</table>

<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>Cisplatin</td>
<td>0.1</td>
<td>15663-27-1</td>
<td>TP2450000</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>Cisplatin</td>
<td>2A</td>
<td>REASONABLY ANTICIPATED</td>
<td>Not Listed</td>
</tr>
</tbody>
</table>

Emergency Overview  
Cisplatin Injection is a solution containing cisplatin, a platinum-containing antineoplastic agent that interferes with DNA synthesis in tumor cells (as well as normal cells) by binding to DNA. It is used to treat some types of cancers. It is cytotoxic, neurotoxic, and in the workplace, should be considered a potential sensitizer, a potential occupational reproductive hazard, harmful to the fetus, and a potential human carcinogen. Following an accidental over-exposure, possible target organs may include the gastrointestinal tract, bone marrow, liver, kidneys, ears (hearing), nervous system, and fetus.

Occupational Exposure Potential  
There are scientific studies that suggest that personnel (e.g. nurses, pharmacists, etc.) who prepare and administer parenteral antineoplastics (e.g. in hospitals) may be at some risk due to...
potential mutagenicity, teratogenicity, and/or carcinogenicity of these agents if workplace exposures are not properly controlled. The actual risk in the workplace is not known.

**Signs and Symptoms**

In the workplace, platinum compounds have been reported to cause allergic skin and respiratory reactions. This material should also be considered irritating to the skin, eyes, and respiratory tract. In clinical use, adverse effects have included severe nausea and vomiting, toxic effects on the kidneys, bone marrow depression, loss of hearing, and neurological effects such as peripheral neuropathies.

**Medical Conditions Aggravated by Exposure**

Pre-existing hypersensitivity to platinum compounds. Pre-existing gastrointestinal, liver, kidney, bone marrow, hearing, or nervous system ailments, or pregnancy.

### 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 aqueous product.

**Fire & Explosion Hazard**

None anticipated for this aqueous product.

**Extinguishing media**

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

**Special Fire Fighting Procedures**

Firefighters should wear self-contained breathing apparatus. Protective equipment and clothing should be worn to minimize contact with the respiratory tract, skin and eyes.

### 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. 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**

Cisplatin is a cytotoxic agent. Appropriate procedures should be implemented during the handling and disposal of cytotoxic antineoplastics agents to minimize potential exposures. Several guidelines on handling cytotoxic antineoplastic agents have been published. There is no general agreement that
Product Name: Cisplatin Injection

all of the procedures recommended in the guidelines are necessary or appropriate. Consult your hygienist or safety professional for your site requirements. Avoid ingestion, inhalation, skin contact, and eye contact. When handling the powder, precautions may include the use of a containment cabinet during the weighing, reconstitution and/or solubilization of this antineoplastic agent. The use of disposable gloves and respiratory protection is recommended. Proper disposal of contaminated vials, syringes, or other materials is required when working with this material.

Storage
No special storage is required for hazard control. However, employees should be trained on the proper storage procedures for anti-neoplastic agents. 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 required for hazard control. Persons with known allergies to platinum compounds, women who are pregnant, or women who want to become pregnant, should consult a health and/or safety professional prior to handling this material.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

<table>
<thead>
<tr>
<th>Component</th>
<th>Type</th>
<th>mg/m3</th>
<th>ppm</th>
<th>µg/m3</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cisplatin</td>
<td>US OSHA 8 Hr PEL</td>
<td>N/A</td>
<td>N/A</td>
<td>2</td>
<td>8hr TWA For platinum, for soluble salts</td>
</tr>
<tr>
<td>Cisplatin</td>
<td>ACGIH 8 Hr TLV</td>
<td>N/A</td>
<td>N/A</td>
<td>2</td>
<td>8hr TWA, For platinum, for soluble salts</td>
</tr>
<tr>
<td>Cisplatin</td>
<td>Hospira EEL</td>
<td>N/A</td>
<td>N/A</td>
<td>0.05</td>
<td>SEN</td>
</tr>
</tbody>
</table>

Respiratory protection
Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols or vapors 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 (N99 or equivalent) is recommended under conditions where airborne 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
When handling this material, disposable gloves should be worn at all times. Further, the use of double gloves is recommended. Disposable gloves made from nitrile, neoprene, polyurethane or natural latex generally have low permeability to chemotherapy agents. Persons known to be allergic to latex rubber should select a non-latex glove. Gloves should be changed regularly, and removed immediately after known contamination. Care should be taken to minimize inadvertent contamination when removing and/or disposing of gloves.

Eye protection
As a minimum, the use of chemical safety goggles is recommended when handling this material.

Engineering Controls
When handling the dry powder, local exhaust ventilation is recommended to minimize employee exposure. The use of an enclosure, such as an approved ventilated cabinet designed to minimize airborne exposures, is recommended.

9. PHYSICAL/CHEMICAL PROPERTIES
Product Name: Cisplatin Injection

Appearance/Physical State  Liquid
Color  Clear, colorless to pale yellow
Odor  Odorless
Odor Threshold:  Not determined
pH:  NA
Melting point/Freezing point:  NA
Initial Boiling Point/Boiling Point Range:  NA
Evaporation Rate:  NA
Flammmability (solid, gas):  NA
Upper/Lower Flammability or Explosive Limits:  NA
Vapor Pressure:  NA
Vapor Density:  NA
Specific Gravity:  1.00
Solubility:  Soluble in water or saline
Partition coefficient: n-octanol/water:  NA
Auto-ignition temperature:  NA
 Decomposition temperature:  NA

10. STABILITY AND REACTIVITY

Reactivity  Not determined.
Chemical Stability  Stable under recommended storage conditions and use.
Hazardous Reactions  Not determined.
Conditions to avoid  Not determined.

Incompatibilities  Platinum therapeutic agents are reported to be incompatible with oxidizing agents of aluminum, sodium bicarbonate, sodium bisulfate, and sodium metabisulfite. Avoid contact with chloride salts.

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

Hazardous Polymerization  Not anticipated to occur with this material.

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>Cisplatin</td>
<td>100%; 0.1%; 100%;</td>
<td>LD50; LD50; LD50;</td>
<td>Oral, Oral, Intravenous, Intravenous</td>
<td>25.8, 32.7, 52.6; 22500; 8, 11; 6.4, 6.6</td>
<td>mg/kg; mg/kg; mg/kg; mg/kg; mg/kg; mg/kg</td>
<td>Rat, Mouse; Rat; Rat, Mouse; Rat,</td>
</tr>
</tbody>
</table>
Product Name: Cisplatin Injection

<table>
<thead>
<tr>
<th></th>
<th>100%</th>
<th>LD50</th>
<th>mg/kg</th>
<th>Mouse</th>
</tr>
</thead>
<tbody>
<tr>
<td>Aspiration Hazard</td>
<td>100%</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal Irritation/Corrosion</td>
<td>None anticipated from normal use of this product. However, inadvertent skin contact with this product may produce irritation.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ocular Irritation/Corrosion</td>
<td>None anticipated from normal use of this product. However, inadvertent eye contact with this product may produce irritation with redness and discomfort.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dermal or Respiratory Sensitization</td>
<td>In the workplace, platinum compounds have been reported to cause allergic skin and respiratory reactions. Hypersensitivity reactions, sometimes severe, have been reported during the clinical use of this product.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Reproductive Effects</td>
<td>The effects of cisplatin on fertility have not been fully evaluated. In animal studies, cisplatin has produced testicular atrophy. Cisplatin is embryotoxic and teratogenic in mice and rats, and embryotoxic in rabbits. In rats, the low-observed-effect level (LOEL) intraperitoneal dosage was 0.25 mg/kg/day for embryolethality. In rabbits, the LOEL dosage was 0.125 mg/kg/day for embryolethality. Cisplatin may cause fetal harm when given to pregnant women.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mutagenicity</td>
<td>Cisplatin was positive in a battery of in vitro and in vivo genotoxicity assays to detect mutagenic and clastogenic activity.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Carcinogenicity</td>
<td>Cisplatin has been shown to be carcinogenic in mice and rats. Secondary malignancies have been reported in cancer patients treated with cisplatin in combination with other chemotherapeutic agents and/or radiation. Cisplatin is listed by IARC as 2A-probable human carcinogen, and by NTP as Group 2 – reasonably anticipated human carcinogen.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Target Organ Effects</td>
<td>This material should be considered irritating to the skin, eyes, and respiratory tract. Following an accidental over-exposure, possible target organs may include the gastrointestinal tract, bone marrow, liver, kidneys, ears (hearing), nervous system, and fetus.</td>
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</tbody>
</table>

12. ECOLOGICAL INFORMATION

<p>| | | | | |</p>
<table>
<thead>
<tr>
<th></th>
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</thead>
<tbody>
<tr>
<td>Aquatic Toxicity</td>
<td>Not determined for product.</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Persistence/Biodegradability</td>
<td>Not determined for product. Cisplatin was reported to be non-biodegradable using a 21-day OECD screening test. If released into the environment, cisplatin, and its transformation products, will leach through soil based on its water solubility and stability.</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>Bioaccumulation</td>
<td>Not determined for product.</td>
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<td></td>
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</tr>
<tr>
<td>Mobility in Soil</td>
<td>Not determined for product.</td>
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</tbody>
</table>

13. DISPOSAL CONSIDERATIONS
**Product Name: Cisplatin Injection**

**Waste Disposal**

All pharmaceutical wastes must be properly characterized. Disposal should be performed in accordance with the federal, state or local regulatory requirements.

**Container Handling and Disposal**

Dispose of containers 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>Cisplatin</td>
<td>Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Not Listed</td>
<td>Listed</td>
</tr>
<tr>
<td>RCRA Status</td>
<td>Not Listed</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>U.S. OSHA</td>
<td>Carcinogen</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Classification</td>
<td>Possible Sensitizer</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Target Organ Toxin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Reproductive Toxin</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Irritant</td>
<td></td>
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</tbody>
</table>

**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 - Not Applicable

**Hazard Category**

**Signal Word**

**Symbol**

**Prevention**

P260 - Do not breathe dust/fume/gas/mist/vapours/spray.

**Hazard Statement**

H00 - Not Applicable

**Response:**

IF SWALLOWED: Immediately call a POISON CENTER or doctor. Rinse mouth.

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 a doctor.

IF ON SKIN: Wash with plenty of soap and water. If skin irritation or rash occurs, seek medical...
Product Name: Cisplatin Injection

attention. Take off contaminated clothing and wash 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.

If exposed or concerned, get medical attention.

**EU Classification**

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

**Classification(s):** HL00 - Not Applicable

**Symbol:**

**Indication of Danger:**

**Risk Phrases:** R00 - Not Applicable

**Safety Phrases:**

- S23 - Do not breathe vapour.
- S24/25 - Avoid contact with skin and 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. 11/03/2011
Obsolete Date: Thu. 11/11/2010
**Product Name: Cisplatin Injection**

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