

# SAFETY DATA SHEET



**Product Name: Cisplatin Injection**

## 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

<b>Manufacturers Name And Address</b>	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA	Hospira Healthcare Corporation 1111 Dr.-Frederik-Philips, Suite 600 Saint-Laurent, Québec H4M 2X6
<b>Emergency Telephone</b>	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418 1 866 488 6088 Option 4 (Canada)	
<b>Hospira, Inc., Non-Emergency</b>	224 212-2000	
<b>Material Name</b>	Cisplatin Injection	
<b>Synonyms</b>	Cis-Diamminodichloroplatinum; platinum (II),diaminedichloro-cis-; Platinum diamminodichloride.	

## 2. HAZARD(S) IDENTIFICATION

**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 reproductive hazard, and a potential human carcinogen. Based on clinical use, possible target organs may include the gastrointestinal tract, bone marrow, liver, kidneys, ears (hearing), and nervous system.

### U.S. OSHA GHS Classification

<b>Physical Hazards</b>	<b>Hazard Class</b>	<b>Hazard Category</b>
	Not Classified	Not Classified

<b>Health Hazards</b>	<b>Hazard Class</b>	<b>Hazard Category</b>
	Sensitization – Respiratory	1
	Sensitization - Skin	1
	Toxic to Reproduction	2
	Carcinogenicity	2

**Label Element(s)**

**Pictogram**



**Signal Word**

Danger

**Hazard Statement(s)**

May cause allergy or asthma symptoms or breathing difficulties if inhaled  
May cause an allergic skin reaction  
Suspected of damaging fertility or the unborn child  
Suspected of causing cancer

**Precautionary Statement(s)**

**Prevention**

Obtain special instructions before use  
Do not handle until all safety precautions have been read and understood  
Wear protective gloves/protective clothing/eye protection/face protection  
Avoid breathing vapors/spray  
In case of inadequate ventilation, wear respiratory protection  
Contaminated work clothing must not be allowed out of the workplace  
Wash hands thoroughly after handling.

**2. HAZARD(S) IDENTIFICATION: continued**

**Response** Get medical attention if you feel unwell.

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 ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a doctor. If exposed or concerned: Get medical advice/attention.

**3. COMPOSITION/INFORMATION ON INGREDIENTS**

**Ingredient Name** Cisplatin  
**Chemical Formula**  $H_6N_2PtCl_2$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Cisplatin	0.1	15663-27-1	TP2450000

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.

**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 such as carbon dioxide, dry chemical extinguishing powder or foam.

**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** Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill control procedures. 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** 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 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**

Component	Exposure Limits			
	OSHA-PEL	ACGIH-TLV	AIHA WEEL	Hospira EEL
Cisplatin	8-hr TWA: 2 mcg/m <sup>3</sup> as platinum, for soluble salts.	8-hr TWA: 2 mcg/m <sup>3</sup> as platinum, for soluble salts.	8-hr TWA: Not Established	8-hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit  
 ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.  
 AIHA WEEL: Workplace Environmental Exposure Level  
 EEL: Employee Exposure Limit.  
 TWA: 8-hour Time Weighted Average.

**Respiratory Protection** Respiratory protection is normally not needed during intended product use. However, if the generation of 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 (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** If handling a 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

Appearance/Physical State	Vials containing a clear, colorless to pale yellow solution
Odor	Odorless
Odor Threshold	NA
pH	NA
Melting point/Freezing Point	NA
Initial Boiling Point/Boiling Point Range	NA
Flash Point	NA
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	1.0
Solubility	Soluble in water or saline
Partition Coefficient: n-octanol/water	NA
Auto-ignition Temperature	NA
Decomposition Temperature	NA
Viscosity	NA

## 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	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 (NO <sub>x</sub> ), oxides of platinum, and hydrogen chloride vapors.
Hazardous Polymerization	Not anticipated to occur with this product.

## 11. TOXICOLOGICAL INFORMATION

**Acute Toxicity** - Not determined for the product formulation. Information for the active ingredient is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Cisplatin	100	LD50	Oral	25.8 32.7, 52.6	mg/kg mg/kg	Rat Mouse
*Cisplatin	0.1	LD50	Oral	22,500	mg/kg	Rat
Cisplatin	100	LD50	Intravenous	8 11	mg/kg mg/kg	Rat Mouse
Cisplatin	100	LD50	Intraperitoneal	6.4 6.6	mg/kg mg/kg	Rat Mouse

LD50 is the dosage producing 50% mortality

\*BMS MSDS \*

**11. TOXICOLOGICAL INFORMATION:** continued

<b>Occupational Exposure Potential</b>	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.		
<b>Signs and Symptoms</b>	None anticipated from normal handling of this product. 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.		
<b>Aspiration Hazard</b>	None anticipated from normal use of this product.		
<b>Dermal Irritation/Corrosion</b>	None anticipated from normal handling of this product. However, inadvertent skin contact with this product may produce irritation.		
<b>Ocular Irritation/Corrosion</b>	None anticipated from normal handling of this product. However, inadvertent eye contact with this product may produce irritation with redness and discomfort.		
<b>Dermal or Respiratory Sensitization</b>	None anticipated from normal handling of this product. 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.		
<b>Reproductive Effects</b>	None anticipated from normal handling of this product. 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 embryoletality. In rabbits, the LOEL dosage was 0.125 mg/kg/day for embryoletality. Cisplatin may cause fetal harm when given to pregnant women.		
<b>Mutagenicity</b>	Cisplatin was positive in a battery of <i>in vitro</i> and <i>in vivo</i> genotoxicity assays to detect mutagenic and clastogenic activity.		
<b>Carcinogenicity</b>	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.		
<b>Carcinogen Lists</b>	<b>IARC:</b> 2A- probable human carcinogen	<b>NTP:</b> Group 2 – reasonably anticipated human carcinogen	<b>OSHA:</b> Not listed
<b>Specific Target Organ Toxicity – Single Exposure</b>	NA		
<b>Specific Target Organ Toxicity – Repeat Exposure</b>	Based on clinical use, possible target organs may include the gastrointestinal tract, bone marrow, liver, kidneys, ears (hearing), and nervous system.		

## 12. ECOLOGICAL INFORMATION

<b>Aquatic Toxicity</b>	Not determined for product.
<b>Persistence/Biodegradability</b>	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.
<b>Bioaccumulation</b>	Not determined for product.
<b>Mobility in Soil</b>	Not determined for product.

## 13. DISPOSAL CONSIDERATIONS

<b>Waste Disposal</b>	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
<b>Container Handling and Disposal</b>	Dispose of container and unused contents in accordance with federal, state and local regulations.

## 14. TRANSPORTATION INFORMATION

<b>ADR/ADG/ DOT STATUS</b>	Not regulated
<b>Proper Shipping Name</b>	NA
<b>Hazard Class</b>	NA
<b>UN Number</b>	NA
<b>Packing Group</b>	NA
<b>Reportable Quantity</b>	NA
<b>ICAO/IATA STATUS</b>	Not regulated
<b>Proper Shipping Name</b>	NA
<b>Hazard Class</b>	NA
<b>UN Number</b>	NA
<b>Packing Group</b>	NA
<b>Reportable Quantity</b>	NA
<b>IMDG STATUS</b>	Not regulated
<b>Proper Shipping Name</b>	NA
<b>Hazard Class</b>	NA
<b>UN Number</b>	NA
<b>Packing Group</b>	NA
<b>Reportable Quantity</b>	NA

Notes: DOT - US Department of Transportation Regulations

## 15. REGULATORY INFORMATION

<b>US TSCA Status</b>	Exempt. However, cisplatin and sodium chloride are listed on the TSCA Inventory
<b>US CERCLA Status</b>	Not listed
<b>US SARA 302 Status</b>	Not listed
<b>US SARA 313 Status</b>	Not listed
<b>US RCRA Status</b>	Not listed
<b>US PROP 65 (Calif.)</b>	This product is, or contains a chemical(s) known to the State of California to cause cancer.

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

**15. REGULATORY INFORMATION: continued**

**GHS/CLP 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.

<b>Hazard Class</b>	<b>Hazard Category</b>	<b>Pictogram</b>	<b>Signal Word</b>	<b>Hazard Statement</b>
NA	NA	NA	NA	NA

**Prevention**

Obtain special instructions before use  
 Do not handle until all safety precautions have been read and understood  
 Wear protective gloves/protective clothing/eye protection/face protection  
 Avoid breathing vapors/spray  
 In case of inadequate ventilation, wear respiratory protection  
 Contaminated work clothing must not be allowed out of the workplace  
 Wash hands thoroughly after handling.

**Response**

Get medical attention if you feel unwell.

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 ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a doctor. If exposed or concerned: Get medical advice/attention.

**EU Classification\***

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

**Classification(s)**

NA

**Symbol**

NA

**Indication of Danger**

NA

**Risk Phrases**

R42/43: May cause sensitization by inhalation and skin contact

**Safety Phrases**

S23: Do not breathe vapor/spray  
 S24: Avoid contact with the skin  
 S25: Avoid contact with eyes  
 S37/39: Wear suitable gloves and eye/face protection

**16. OTHER INFORMATION**

Notes: NA

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
LD <sub>50</sub>	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
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS  
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**Disclaimer:**

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