



## MATERIAL SAFETY DATA SHEET

**Product Name: Carboplatin Injection**

### 1. CHEMICAL PRODUCT AND COMPANY INFORMATION

<b>Manufacturer Name And Address</b>	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA	Hospira Australia Pty Ltd 1 Lexia Place Mulgrave VIC 3170 AUSTRALIA
<b>Emergency Telephone #'s</b>	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia (02) 8014 4880	
<b>Hospira, Inc., Non-Emergency</b>	224 212-2055	
<b>Material Name</b>	Carboplatin Injection	
<b>Synonyms</b>	Platinum, diammine(1,1-cyclobutanedicarboxylato(2-)-O,O'), (SP-4-2); cis-Diammine(1,1-cyclobutanedicarboxylato)platinum(II); Paraplatin	

### 2. HAZARD INFORMATION / CLASSIFICATION

<b>Emergency Overview</b>	Carboplatin Injection contains carboplatin, an analog of cisplatin with similar actions and uses. It is used alone or combined with other antineoplastics to treat some types of cancer. 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.		
<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 materials if workplace exposures are not properly controlled. The actual risk in the workplace is not known.		
<b>Signs and Symptoms</b>	In the workplace, platinum compounds have been reported to cause allergic skin and respiratory reactions. This material should 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>Medical Conditions Aggravated by Exposure</b>	Pre-existing hypersensitivity to platinum compounds. Pre-existing gastrointestinal, liver, kidney, bone marrow, hearing, and nervous system ailments, or pregnancy.		
<b>Carcinogen Lists:</b>	<b>IARC:</b> Not listed	<b>NTP:</b> Not listed	<b>OSHA:</b> Not listed

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

<b>Ingredient Name</b>	Carboplatin
<b>Chemical Formula</b>	$C_6H_{12}N_2O_4$ Pt

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Carboplatin	1	41575-94-4	TP2300000

Non hazardous ingredients include Water for Injection, USP.

#### **4. FIRST AID MEASURES**

<b>Eye Contact</b>	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.
<b>Skin Contact</b>	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.
<b>Inhalation</b>	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Ingestion</b>	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

#### **5. FIRE FIGHTING MEASURES**

<b>Flammability</b>	None anticipated from this aqueous product.
<b>Fire &amp; Explosion Hazard</b>	None anticipated from this aqueous product.
<b>Extinguishing Media</b>	As with any fire, use extinguishing media appropriate for primary cause of fire.
<b>Special Fire Fighting Procedures</b>	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**

<b>Spill Cleanup and Disposal</b>	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**

<b>Handling</b>	Carboplatin 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.
-----------------	---

## 7. HANDLING AND STORAGE: continued

- Handling (continued)** Avoid ingestion, inhalation, skin contact, and eye contact. If handling a 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 antineoplastic agents. For product protection, follow USP controlled room temperature storage recommendations noted on the product case label or the primary container label.
- Special Precautions** 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	Hospira EEL	Other Limits
Carboplatin	8-hr TWA: 0.002 mg/m <sup>3</sup> for platinum, for soluble salts.	8-hr TWA: 0.002 mg/m <sup>3</sup> for platinum, for soluble salts.	8-hr TWA: Not Established	NA

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 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

<b>Appearance/Physical State</b>	Sterile, clear aqueous solution in a vial
<b>Odor</b>	Odorless
<b>Odor Threshold:</b>	Not determined.
<b>pH:</b>	5-7 for a 1% solution
<b>Melting point/Freezing point:</b>	NA
<b>Initial Boiling Point/Boiling Point Range</b>	NA
<b>Evaporation Rate:</b>	NA
<b>Flash Point:</b>	NA
<b>Flammability (solid, gas):</b>	NA
<b>Upper/Lower Flammability or Explosive Limits:</b>	NA
<b>Vapor Pressure</b>	NA
<b>Vapor Density (Air =1)</b>	NA
<b>Evaporation Rate</b>	NA
<b>Specific Gravity</b>	NA
<b>Solubility</b>	Soluble in water at a rate of approximately 14 mg/mL, It is virtually insoluble in ethanol, acetone, and dimethylacetamide.
<b>Partition coefficient: n-octanol/water:</b>	NA
<b>Auto-ignition temperature</b>	NA
<b>Decomposition temperature</b>	NA

## 10. STABILITY AND REACTIVITY

<b>Reactivity</b>	Not determined.
<b>Chemical Stability</b>	Stable under standard use and storage conditions.
<b>Hazardous Reactions</b>	Not determined
<b>Conditions to avoid</b>	Not determined
<b>Incompatibilities</b>	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.
<b>Hazardous Decomposition Products</b>	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).
<b>Hazardous Polymerization</b>	Not anticipated to occur with this product.

## 11. TOXICOLOGICAL INFORMATION

### Acute Toxicity

<b>Ingredient(s)</b>	<b>Percent</b>	<b>Test Type</b>	<b>Route of Administration</b>	<b>Value</b>	<b>Units</b>	<b>Species</b>
Carboplatin	100	LD50	Oral	343	mg/kg	Rat
Carboplatin	100	LD50	Intravenous	61	mg/kg	Rat
				89.4	mg/kg	Mouse
				31.2	mg/kg	Dog
Carboplatin	100	LD50	Intraperitoneal	118	mg/kg	Mouse
				72	mg/kg	Rat

LD50 is the dosage producing 50% mortality

## **11. TOXICOLOGICAL INFORMATION: continued**

<b>Aspiration Hazard</b>	None anticipated from normal handling of this material.
<b>Dermal Irritation/Corrosion</b>	None anticipated from normal use of this product. However, inadvertent skin contact with this product may produce redness and discomfort.
<b>Ocular Irritation/Corrosion</b>	None anticipated from normal use of this product. However, inadvertent eye contact with this product may produce irritation, redness and discomfort.
<b>Dermal or Respiratory Sensitization</b>	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. Persons with known allergies to platinum should consult a health or safety professional prior to handling open containers of this material.
<b>Reproductive Effects</b>	Carboplatin has been shown to be embryotoxic and teratogenic in rats receiving the drug during organogenesis. Administration of carboplatin to male and female rats at dosages up to 4 mg/kg produced suppression of body weight in the adults and other signs of toxicity, but did not appear to impair fertility. Fetal mortality was increased, and there were decreases in intrauterine growth and skeletal ossification, consistent with general toxicity, but no increase in birth defects. In a subsequent study, when the dosage was increased to 6 mg/kg/day, an increase in congenital anomalies, including gastroschisis, ventriculomegaly, and skeletal anomalies, was noted. Carboplatin may cause fetal harm when given to pregnant women.
<b>Mutagenicity</b>	Carboplatin is genotoxic in both in vitro and in vivo mutagenesis assays, including the Ames bacterial cell assay, the Chinese hamster ovary cell assay, and the mouse lymphoma assay.
<b>Carcinogenicity</b>	The carcinogenic potential of carboplatin has not been fully evaluated. By analogy, compounds with similar mechanisms of action and mutagenic potential, such as cisplatin, are considered potential human carcinogens. Carboplatin should be considered a possible human carcinogen.
<b>Target Organ Effects</b>	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.

## **12. ECOLOGICAL INFORMATION**

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

Notes:

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

<b>Waste Disposal</b>	All wastes must be properly characterized. Disposal should be performed in accordance with the federal, state or local regulatory requirements.
<b>Container Handling and Disposal</b>	Dispose of containers 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

**15. REGULATORY INFORMATION**

**TSCA Status** Exempt  
**CERCLA Status** Not listed  
**SARA 302 Status** Not listed  
**SARA 313 Status** Not listed  
**RCRA Status** Not listed  
**PROP 65 (Calif.)** This product is, or contains chemical(s) known to the State of California to cause developmental toxicity.






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

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

**15. REGULATORY INFORMATION: continued**

**GHS Classification**

\*Where medicinal products are not exempt, the recommended GHS workplace classification for this product is as follows:

<b>Hazard Class</b>	Acute Oral Toxicity	Eye Irritation	Skin Irritation	Respiratory Sensitization	Toxic to Reproduction	Mutagenicity	Target Organ Toxicity
<b>Hazard Category</b>	Unclassified	2B	2	1	2	2	2
<b>Symbol</b>	NA	NA					
<b>Signal Word</b>	NA	Warning	Warning	Danger	Warning	Warning	Warning
<b>Hazard Statement</b>	NA	Causes eye irritation	Causes skin irritation May cause an allergic skin reaction	May cause allergic or asthmatic symptoms or breathing difficulties if inhaled.	Suspected of damaging fertility or the unborn child.	Suspected of causing genetic defects if ingested.	May cause damage to the gastrointestinal system, bone marrow, liver, kidneys, ears (hearing), and nervous system through prolonged or repeated exposure.

**GHS Precautionary Statements:**

**Prevention:**

Do not eat, drink or smoke when using this product.  
Obtain special instructions before use.  
Do not handle until all safety precautions have been read and understood.  
Use personal protective equipment as required.  
Avoid breathing dust or vapors.  
In case of inadequate ventilation wear respiratory protection.  
Wear protective gloves.  
Wash hands thoroughly after handling.  
Contaminated work clothing should not be allowed out of the workplace.

**Response:**

IF SWALLOWED: Call a POISON CENTER or doctor if you feel unwell.

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 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.

## Product Name: Carboplatin Injection



### 15. REGULATORY INFORMATION: continued

#### EU Classification

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

<b>Classification(s):</b>	Harmful	Irritant Skin Sensitizer	Mutagen Category 2	Toxic for Reproduction Category 2	Carcinogen Category 3	Respiratory Sensitizer
<b>Symbol:</b>						
<b>Indication of Danger:</b>	Xn	Xi/Xn	T	T	Xn	Xn

#### Risk Phrases:

R22 - Harmful if swallowed  
R36/37/38 - Irritating to eyes, respiratory system and skin  
R40 - Limited evidence of a carcinogenic effect  
R42 - May cause sensitization by inhalation;  
R43 - May cause sensitization by skin contact  
R46 - May cause heritable genetic damage  
R48/25 - Danger of serious damage to health by prolonged exposure if swallowed  
R60 - May impair fertility  
R61 - May cause harm to the unborn child  
R64 - May cause harm to breastfed babies

#### Safety Phrases:

S22: Do not breathe dust  
S24: Avoid contact with the skin  
S36/37/39: Wear suitable protective clothing, gloves and eye/face protection.  
S60: This material and its container must be disposed of as hazardous waste

### 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
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average



**Product Name: Carboplatin Injection**



**16. OTHER INFORMATION: continued**

MSDS Coordinator: Global Occupational Toxicology  
Date Prepared: November 5, 2009

**Disclaimer:**

The information and recommendations contained herein are based upon tests believed to be reliable. However, Hospira does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. Hospira assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.