SAFETY DATA SHEET

Product Name: Carboplatin Injection

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA	Hospira Australia Pty Ltd 1 Lexia Place Mulgrave VIC 3170 AUSTRALIA
Emergency Telephone	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418	
Hospira, Inc., Non-Emergency	224 212-2000	
Material Name	Carboplatin Injection	
Synonyms	Platinum, diammine(1,1-cyclobutanedicarboxylato(2-)-O,O')-, (SP-4-2); cis-Diammine(1,1-cyclobutanedicarboxylato)platinum(II); Paraplatin	

2. HAZARD(S) IDENTIFICATION

Emergency Overview

Carboplatin Injection is a solution containing carboplatin, an analog of cisplatin with similar actions and uses. It is used alone or combined with other antineoplastics to treat some types of cancers. It is cytotoxic, neurotoxic, and in the workplace, should be considered a potential sensitizer and a potential occupational reproductive hazard. 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

Physical Hazards	**Hazard Class**	**Hazard Category**
	Not Classified	Not Classified

Health Hazards	**Hazard Class**	**Hazard Category**
	Sensitization – Respiratory	1
	Sensitization – Skin	1
	Germ Cell Mutagenicity	2
	Toxic to Reproduction	2
	STOT - RE	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 causing genetic defects
Suspected of damaging fertility or the unborn child
May cause damage to organs through prolonged or repeated exposure

2. HAZARD(S) IDENTIFICATION: continued

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.
Do not breathe vapor or 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 INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a doctor.

IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get 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

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient Name Carboplatin
Chemical Formula $C_6H_{12}N_2O_4$ Pt

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

Non hazardous ingredients include Water for Injection.

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

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.

Avoid ingestion, inhalation, skin contact, and eye contact. 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 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

	Exposure Limits			
Component	**OSHA-PEL**	**ACGIH-TLV**	**AIHA WEEL**	**Hospira EEL**
Carboplatin	8-hr TWA: 0.002 mg/m3 for platinum, for soluble salts.	8-hr TWA: 0.002 mg/m3 for 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 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.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION: continued

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	Sterile, clear aqueous solution in a vial
Odor	Odorless
Odor Threshold	NA
pH	5-7 for a 1% solution
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	NA
Solubility	Soluble in water at a rate of approximately 14 mg/mL. Virtually insoluble in ethanol, acetone, and dimethylacetamide
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 carbon oxides (COx), nitrogen oxides (NOx), and oxides of platinum.
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
Carboplatin	100	LD50	Oral	343	mg/kg	Rat
Carboplatin	100	LD50	Intravenous	61 89.4 31.2	mg/kg mg/kg mg/kg	Rat Mouse Dog
Carboplatin	100	LD50	Intraperitoneal	118 72	mg/kg mg/kg	Mouse Rat

LD50 is the dosage producing 50% mortality

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 materials if workplace exposures are not properly controlled. The actual risk in the workplace is not known. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms

None anticipated from normal handling of this material. 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.

Aspiration Hazard

None anticipated from normal handling of this material.

Dermal Irritation/Corrosion

None anticipated from normal use of this product. However, inadvertent skin contact with this product may produce redness and discomfort.

Ocular Irritation/Corrosion

None anticipated from normal use of this product. However, inadvertent eye contact with this product may produce irritation, redness and discomfort.

Dermal or Respiratory Sensitization

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.

Reproductive Effects

None anticipated from normal handling of this material. 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. FDA Pregnancy Category D.

Mutagenicity

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.

Carcinogenicity

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.

11. TOXICOLOGICAL INFORMATION: continued

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

Specific Target Organ Toxicity – Single Exposure	NA
Specific Target Organ Toxicity – Repeat Exposure	Based on clinical use, possible target organs may include the gastrointestinal tract, bone marrow, liver, kidneys, ears (hearing), and nervous system.

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.

Notes:

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
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

US TSCA Status	Exempt
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US PROP 65 (Calif.)	This product is, or contains a 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

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.

Hazard Class	Hazard Category	Pictogram	Signal Word	Hazard Statement
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.
Do not breathe vapor or 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 INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a doctor.

IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get 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.

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_{50}	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
Date Prepared: October 17, 2012
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