



## MATERIAL SAFETY DATA SHEET

**Product Name: Carboplatin Injection**

### 1. CHEMICAL PRODUCT AND COMPANY INFORMATION

**Manufacturer Name And Address** Hospira Inc.  
275 North Field Drive  
Lake Forest, Illinois USA  
60045

Hospira Australia Pty Ltd  
1 Lexia Place  
Mulgrave, VIC 3170  
Australia

**Emergency Telephone** CHEMTREC: North America: 800-424-9300;  
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**Hospira, Inc., Non-Emergency** 224-212-2000

**Product Name** Carboplatin Injection

**Synonyms** Platinum, diammine(1,1-cyclobutanedicarboxylato(2-)-O,O')-, (SP-4-2); cis-Diammine(1,1-cyclobutanedicarboxylato)platinum(II); Paraplatin

### 2. COMPOSITION/INFORMATION ON INGREDIENTS

**Active Ingredient Name** Carboplatin

**Chemical Formula**  $C_6H_{12}N_2O_4 Pt$

**Preparation** Non hazardous ingredients include Water for Injection, USP.

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

### 3. HAZARD INFORMATION

#### Carcinogen List

| Substance   | IARC       | NTP        | OSHA       |
|-------------|------------|------------|------------|
| Carboplatin | Not Listed | Not Listed | Not Listed |

**Emergency Overview** 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.

**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.

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|  |   |
|--|---|
| <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.   |

### 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 |
|-----------------|--|

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site requirements. 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 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  |                   |     |                   | Note                            |
|-------------|------------------|-------------------|-----|-------------------|---------------------------------|
|             | Type             | mg/m <sup>3</sup> | ppm | µg/m <sup>3</sup> |                                 |
| Carboplatin | US OSHA 8 Hr PEL | 0.002             | N/A | N/A               | For Platinum, For Soluble Salts |
| Carboplatin | ACGIH 8 Hr TLV   | 0.002             | N/A | N/A               | For platinum, For soluble salts |

**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

**Appearance/Physical State** Liquid  
**Color** Sterile, clear aqueous solution in a vial

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|  |  |
|--|--|
| <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>Flammability (solid, gas):</b>                    | NA   |
| <b>Upper/Lower Flammability or Explosive Limits:</b> | NA   |
| <b>Vapor Pressure:</b>                               | NA   |
| <b>Vapor Density:</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 (CO <sub>x</sub> ), nitrogen oxides (NO <sub>x</sub> ), and oxides of platinum. |
| <b>Hazardous Polymerization</b>         | 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:

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

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|  |  |  |  |    |       |     |
|--|--|--|--|----|-------|-----|
|  |  |  |  | 72 | mg/kg | Rat |
|--|--|--|--|----|-------|-----|

|  |  |
|--|--|
| <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 determined. |
| <b>Persistence/Biodegradability</b> | Not determined. |
| <b>Bioaccumulation</b>              | Not determined. |
| <b>Mobility in Soil</b>             | Not determined. |

## 13. DISPOSAL CONSIDERATIONS

|                       |  |
|-----------------------|--|
| <b>Waste Disposal</b> | All wastes must be properly characterized. Disposal should be performed in |
|-----------------------|--|

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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

| Substance   | TSCA Status | CERCLA Status | SARA 302 Status | SARA 313 Status | PROP 65 Status |
|-------------|-------------|---------------|-----------------|-----------------|----------------|
| Carboplatin | Not Listed  | Not Listed    | Not Listed      | Not Listed      | Listed         |

**RCRA Status** Not Listed  
**U.S. OSHA Classification** Possible Carcinogen  
Possible Sensitizer  
Target Organ Toxin  
Reproductive Toxin  
Possible Irritant

**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

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for the pure drug substance Carboplatin

|                              |   |
|------------------------------|---|
| <b>Classification(s):</b>    | Not Applicable  |
| <b>Symbol:</b>               | Not Applicable  |
| <b>Indication of Danger:</b> | Not Applicable  |
| <b>Risk Phrases:</b>         | R00 - Not Applicable  |
| <b>Safety Phrases:</b>       | S23 - Do not breathe vapor.<br>S24/25 - Avoid contact with skin and eyes.<br>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

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