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|  | Sagent Pharmaceuticals, Inc. | | | | |
| | Carboplatin Injection | | | Safety Data Sheet (SDS) | |
| | SDS Issue Date: Jan. 27, 2015 | SDS No.: SDS 017 | SDS Version No.: 2.0 | Form No.: R-SOP-009-F001 | Page: 1 of 10 |


Section 1 - Identification



- (a) **Product Identifier:** Carboplatin Injection
- (b) **Product Code:** 25021-202
Common/Trade Name: Paraplatin
Chemical Name: Platinum, diammine [1,1-cyclobutane-dicarboxylato(2-)-0,0']-, (SP-4-2)
Chemical Family: Analog of cisplatin, antineoplastic alkylating agent
- (c) **Product Use:** Pharmaceutical
Product Type: Regulated Prescription Drug
Container Information: Vials
- (d) **Distributor:** Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 700, Schaumburg, IL 60195, 847-908-1600
- (e) **Emergency Telephone:** 866-625-1618

Section 2 - Hazards Identification


- (a) **Classification:** Acute Toxicity, Oral (Unclassified)
Eye Irritation (Category 2B)
Skin Irritation (Category 2)
Respiratory Sensitization (Category 1)
Toxic to Reproduction (Category 2)
Mutagenicity (Category 2)
Target Organ Toxicity (Category 2)
- NFPA Rating**
- | | |
|-------------------|---|
| Health Hazard | 2 |
| Fire Hazard | 0 |
| Reactivity Hazard | 0 |

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| (b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s): | (c) Description of Hazards: |
| <u>Signal Word:</u> | DANGER |
| <u>Hazard Statements:</u> N/A | <ul style="list-style-type: none"> - Causes eye irritation - Causes skin irritation. May cause an allergic skin reaction |

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|--|---|
| (b) Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s): | (c) Description of Hazards: |
|   | <ul style="list-style-type: none"> - 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. |
| <p><u>Precautionary Statements:</u></p> <p><u>Precautionary Statements:</u></p> | <p>PREVENTION</p> <ul style="list-style-type: none"> - 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. <p>RESPONSE</p> <ul style="list-style-type: none"> - 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. |

(d) Unknown Acute Toxicity: N/A

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Section 3 – Composition / Information on Ingredients

| (a) Chemical Name | (b) Common Name / Synonym | % Composition or other measure | (c) CAS No. | (d) Impurities / Stabilizing Additives |
|---|---------------------------|--------------------------------|-------------|--|
| diammine [1,1-cyclobutane-dicarboxylato(2-)-0,0']-, (SP-4-2), | Carboplatin | 1% | 41575-94-4 | N/A |
| Water | Water for Injection | 99 | 7732-18-5 | N/A |

Section 4 - First Aid Measures

Eye Exposure: Move victim away from exposure and into fresh air. If irritation or redness develops, flush eyes with clean water and seek immediate medical attention. For direct contact, hold eyelids apart and flush the affected eye(s) with clean water for at least 15 minutes. Seek medical attention.


Skin Exposure: Remove contaminated shoes and clothing immediately. Flush area with water for at least 15 minutes. If irritation or redness develops and persists, seek medical attention.

Ingestion: If swallowed, seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. If victim is alert, induce vomiting and do not leave victim unattended. Observe victim closely for adequacy of breathing.

Injection: In cases of accidental injection, wash and disinfect area, seek emergency medical attention.

Inhalation: If respiratory symptoms develop, move victim away from source of exposure and into fresh air. If symptoms persist, seek medical attention. If victim is not breathing, clear airway and immediately begin artificial respiration. If breathing difficulties develop, oxygen should be administered by qualified personnel. See immediate medical attention.

Notes to Physician: Victims of chemical exposure must be taken for medical attention. Take a copy of the MSDS to the physician or health professional with victim. Physicians should refer to Section 11 (Toxicological Information) as well as the Physicians Desk Reference for additional treatment information.

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Section 5 –Fire-fighting Measures

- (a) **Extinguishing Media** Water spray, dry chemical, carbon dioxide, or foam as appropriate to surroundings.
- (b) **Hazardous Combustion Products:** During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx) and nitrogen oxides (NOx)
- (c) **Special Protective Equipment / Precautions:** For fires beyond the incipient stage, emergency responders in the immediate hazard area should wear bunker gear. When the potential chemical hazard is unknown, in enclosed or confined spaces, or when explicitly required by DOT, a self-contained breathing apparatus should be worn. In addition, wear other appropriate protective equipment as conditions warrant (see Section 8). Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Move undamaged container from immediate hazard area if it can be done with minimal risk. Cool equipment exposed to fire with water, if it can be done with minimal risk.

Spill: Wear latex or nitrile gloves and safety glasses for small spills.


For large or uncontrolled releases, stay upwind and away from spill. Isolate immediate hazard area and keep unauthorized personnel out. Contain spill if it can be done with minimal risk. Wear appropriate protective equipment including respiratory protection as conditions warrant (see Section 8). Prevent spilled material from entering sewers, storm drains, other unauthorized treatment drainage systems, and natural waterways. Minimize dust generation. Sweep up and package appropriately for disposal. Notify appropriate federal, state, and local agencies. Immediate cleanup of any spill is recommended.

Release to Air: If dusts are generated, reduce exposures by ventilating and preventing the generation of dusts. Wear respiratory protection.

Release to Water: Refer to the local water authority; drain disposal is not recommended. Refer to local, state and federal guidelines.

Section 7 - Handling and Storage

General Handling: **CARBOPLATIN IS A CYTOTOXIC AGENT. ALL WORK PRACTICES MUST BE DESIGNED TO REDUCE HUMAN EXPOSURE TO THE LOWEST LEVEL.** As with all chemicals, avoid getting this product ON YOU or IN YOU. Do not eat, drink, smoke or apply cosmetics while handling this product. Wash hands thoroughly after handling. Particular care in working with this product must be practiced in pharmacies and other preparation areas, during manufacture of this product, and during patient

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administration. Precautions should be taken during the following activities:

- Withdrawal of needles from drug vials.
- Drug transfers using syringes and needles or filter straws.
- Expulsion of air from drug-filled syringes.

DO NOT CLIP OR CRUSH NEEDLE WITH WHICH THIS COMPOUND WAS IN CONTACT. Use of this compound should meet the following provisions.

- Work should be performed in a designated area for working with hazardous drugs;
- Containment devices, such as a Biological Safety Cabinet, should be used;
- Contaminated waste must be properly handled; and

Work areas must be regularly decontaminated.

Storage Conditions: Store at 20 to 25° C (68 to 77° F); excursions permitted from 15° - 30° C (59° - 86° F) [see USP Controlled Room Temperature]. Protect from light. Retain in carton until use.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits


| Compound | Issuer | Type | Exposure Limit |
|-------------|--------|------|-------------------------|
| Carboplatin | OSHA | PEL | 0.002 mg/m ³ |
| | ACGIH | TWA | 0.002 mg/m ³ |
| | ---- | | NE |

(b) Engineering Controls

Ventilation: Use with adequate ventilation such as in a Class II Type B biological safety cabinet.

(c) Individual Protection Measures


| | |
|-------------------------|--|
| Respiratory Protection: | Not normally required for routine, medical administration of this product. A NIOSH approved air purifying respirator with a type 95 particulate filter may be used under conditions where airborne concentrations are expected to exceed exposure limits (see Section 2). Protection provided by air purifying respirators is limited (see manufacturer's respirator selection guide). Use a positive pressure air supplied respirator if there is potential for uncontrolled release, exposure levels are not known, or any other circumstances where air purifying respirators may not provide adequate protection. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed if workplace |
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| | conditions warrant a respirator. |
| Eye Protection: | Safety glasses or goggles. Depending on conditions of use, a face shield may be necessary. |
| Skin Protection: | Use latex, nitrile, or rubber glove. Check gloves for leaks. Wash hands before and after using gloves. |
| Other Protective Equipment: | No special body protection required for routine, medical administration of this product. Wear lab coat, gown, or smock, as appropriate for procedure. |
| Additional Exposure Precautions: | Wash hands following use. No eating, drinking or smoking when handling this product. |

Section 9 - Physical and Chemical Properties

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|-----|---|--|
| (a) | Appearance | Clear, colorless to slightly yellow solution |
| (b) | Odor | No Odor |
| (c) | Odor Threshold | None |
| (d) | pH | 5.0 – 7.0 |
| (e) | Melting Point: | N/A |
| (f) | Initial Boiling Point: | 100°C (212°F) |
| (g) | Flash Point | Not Available |
| (h) | Evaporation Rate: | Not Available |
| (i) | Flammability | Not Flammable |
| (j) | Upper Lower Flammability or Explosion Limits | Not Available |
| (k) | Vapor Pressure: | Not Available |
| (l) | Vapor Density: | Not Available |
| (m) | Relative Density | Not Available |
| (n) | Solubility(ies) | Soluble in water at approximately 14 mg/mL. Virtually insoluble in ethanol, acetone, and dimethylacetamide |
| (o) | Partition Coefficient: n-octanol/water | Not Available |
| (p) | Auto-ignition Temperature | Not Available |
| (q) | Decomposition Temperature | Not Available |
| (r) | Viscosity | Not Available |

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Section 10 - Stability and Reactivity


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|------------|---|---|
| (a) | Reactivity | Not determined |
| (b) | Chemical Stability | Stable at normal temperature and pressures. |
| (c) | Possibility of Hazardous Reactions | Hazardous polymerization will not occur |
| (d) | Conditions to Avoid | Protect from light. |
| (e) | Incompatible Materials | This product is generally compatible with other common materials in a medial facility. Contact with aluminum may lead to the formation of a platinum precipitate. |
| (f) | Hazardous Decomposition Products | Oxides of carbon and nitrogen and platinum-containing compounds with possible carcinogenic potential. |

Section 11 - Toxicological Information

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| (a) | Likely Routes of Exposure | May be absorbed by ingestion, inhalation or injection. |
| (b) | Symptoms related to the physical, chemical and toxicological characteristics | CARBOPLATIN IS A CYTOTOXIC AGENT. Toxic if injected or swallowed. Eye irritant. May cause damage to the kidneys, bone marrow, blood, liver, nervous and gastrointestinal systems. Harmful to the fetus. May cause allergic skin and/or respiratory reactions. |
| (c) | Delayed and immediate effects and also chronic effects from short and long term exposure | Effects of overexposure may include decreased blood platelets, granulocytes and white blood cells, fever, anemia, nausea, vomiting, abdominal pain, diarrhea, constipation, peripheral neuropathy, visual disturbances, change in taste, abnormal renal and liver function tests, decreased serum electrolytes, rash, hives, redness, itching, hearing loss, vision changes, bronchospasms and decreased blood pressure. Severe injection overexposure may be fatal. |

(d) Acute Toxicity

| Component | Type | Route | Species | Dosage |
|-------------|------------------|-------|---------|------------|
| Carboplatin | LD ₅₀ | Oral | Rat | 343 mg/kg |
| Carboplatin | LD ₅₀ | IP | Mouse | 150 mg/kg |
| Carboplatin | LD ₅₀ | SubQ | Rat | 72 mg/kg |
| Carboplatin | LD ₅₀ | IV | Rat | 61 mg/kg |
| Carboplatin | LD ₅₀ | IV | Mouse | 89.4 mg/kg |

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|-------------|------------------|----|-----|------------|
| Carboplatin | LD ₅₀ | IV | Dog | 31.2 mg/kg |
|-------------|------------------|----|-----|------------|

Carboplatin was positive in genetic toxicity tests. It has been shown to be mutagenic in bacteria and has produced chromosomal aberrations in animal cells in culture. It may cause fetal harm in pregnant women. Additional reproductive health and toxicity data is available from the National Institute of Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS).

(e) Hazardous Chemical Listings

NTP: Not Listed

IARC: Not Listed

OSHA: Not Listed

Section 12 - Ecological Information


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|--|---|
| (a) Ecotoxicity | This product may be harmful to aquatic plant and animal life in contaminated bodies of water, especially if released in large quantities. |
| (b) Persistence and degradability | It is anticipated that this compound will decompose into a variety of organic compounds |
| (c) Bioaccumulative potential | Not available |
| (d) Mobility in soil | Not available |
| (e) Other Adverse Effects | Not available |

Section 13 - Disposal Considerations

Dispose of waste in accordance with all applicable Federal, State and local laws. Incineration at a licensed facility is recommended.

Section 14 - Transport Information

| | |
|---|---------------|
| (a) UN Number | Not Available |
| (b) UN Proper Shipping Name | Not Available |
| (c) Transport Hazard Class(es) | Not Available |
| (d) Packing Group | Not Available |
| (e) Environmental Hazards | Not Available |
| (f) Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code) | Not Available |
| (g) Special Precautions | Not Available |

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DOT: Not Regulated
ICAO/IATA: Not Regulated
IMDG: Not Regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

TSCA - Exempt
 CERCLA - Not on this list
 SARA 302 - Not on this list
 SARA 311/312 – Acute and Chronic
 SARA 313 - Not on this list
 OSHA – Possible Irritant, Possible Sensitizer, Reproductive Toxin, Possible Carcinogen, Target Organ Toxin

Carboplatin is a chemical known to the State of California to cause developmental effects.

Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:

Sagent Pharmaceuticals, Inc.
 1901 N. Roselle Rd, Suite 700
 Schaumburg, IL 60195
 847-908-1600

Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

| | |
|------------|---|
| ACGIH | American Conference of Governmental Industrial Hygienists |
| AICS | Australian Inventory of Chemical Substances |
| AIHA | American Industrial Hygiene Association |
| ANSI | American National Standards Institute |
| CAS Number | Chemical Abstract Service Registry Number |

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| CERCLA | Comprehensive Environmental Response Compensation and Liability Act (of 1980) |
| CHAN | Chemical Hazard Alert Notice |
| CHEMTREC | Chemical Transportation Emergency Center |
| DOT | Department of Transportation |
| DSL | Domestic Substances List |
| ECHA | European Chemicals Agency |
| EINECS | European Inventory of Existing Commercial Chemical Substances |
| ELINCS | European List of Notified Chemical Substances |
| EPA | Environmental Protection Agency |
| GHS | Globally Harmonized System of Classification and Labelling of Chemicals |
| HEPA | High Efficiency Particulate Air (Filter) |
| HMS | Hazardous Materials Identification System |
| IARC | International Agency for Research on Cancer |
| ICAO/IATA | International Civil Aviation Organization/International Air Transport Association |
| IMDG | International Maritime Dangerous Goods |
| IMO | International Maritime Organization |
| KOW | Octanol/Water Partition Coefficient |
| LEL | Lower Explosive Limit |
| MSDS | Material Safety Data Sheet |
| MSHA | Mine Safety and Health Administration |
| NA | Not Applicable, except in Section 14 where NA = North America |
| NE | Not Established |
| NADA | New Animal Drug Application |
| NAIF | No Applicable Information Found |
| NCI | National Cancer Institute |
| NDSL | Non-Domestic Substances List |
| NFPA | National Fire Protection Association |
| NIOSH | National Institute for Occupational Safety and Health |
| NPDES | National Pollutant Discharge Elimination System |
| NOS | Not Otherwise Specified |
| NTP | National Toxicology Program |
| OSHA | Occupational Safety and Health Administration |
| OEL | Occupational Exposure Limit |
| PEL | Permissible Exposure Limit (OSHA) |
| RCRA | Resource Conservation and Recovery Act |
| RQ | Reportable Quantity |
| RTECS | Registry of Toxic Effects of Chemical Substances |
| SARA | Superfund Amendments and Reauthorization Act |
| SDS | Safety Data Sheet |
| STEL | Short Term Exposure Limit |
| TLV | Threshold Limit Value (ACGIH) |
| TPQ | Threshold Planning Quantity |
| TSCA | Toxic Substances Control Act |
| TWA | Time Weighted Average/8 Hours Unless Otherwise Noted |
| UEL | Upper Explosive Limit |
| UN | United Nations |
| USP | United States Pharmacopeia |
| WEEL | Workplace Environmental Exposure Level (AIHA) |
| WHMIS | Workplace Hazardous Materials Information System |