



300 Northfield Road  
 Bedford, OH 44146  
 Telephone: (440) 232-3320  
 -or- (800) 562-4797

**MATERIAL SAFETY DATA SHEET**

**Section I - IDENTITY**

**Common/Trade Name:** Carboplatin 12.5 mg/mL; 4, 12, and 36 mL vials  
**Chemical Names:** Platinum, diammine(1,1-cyclobutanedicarboxylato(2-)-O,O')-, (SP-4-2)-  
**Synonyms:** Paraplatin ®, Diammine (1,1-cyclobutanedicarboxylato)platinum (II), NSC-241240,  
**Manufacturer's Name:** BEN VENUE LABORATORIES, INC.  
**Address:** 300 NORTHFIELD ROAD  
 BEDFORD, OH 44146  
**Emergency Telephone Number:** Chemtrec: 1(800)424-9300  
**Telephone Number for Info.:** (800)562-4797 or (440)232-3320  
**Medical Emergency:** Professional Services: 1(800)521-5169  
**Date Prepared:** April 11, 2005

**Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION**

<u>Component</u>	<u>%</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>Other Limits</u>	
				<u>ACGIH TLV</u>	
Carboplatin	98.75	41575-94-4	2 ug/m <sup>3</sup> (as Platinum)	<b>Recommended</b>	
				2 ug/m <sup>3</sup> (as Platinum)	0.9 ug/m <sup>3</sup> (BVL OEL)
Mannitol	1.25	69-65-8	NONE	NONE	NONE

Carboplatin is a sterile injectable lyophilized drug provided in a vial.

**Section III - HEALTH HAZARD DATA**

**Routes of Entry:** Product may be absorbed by ingestion, inhalation or injection.

**Health Hazard (Acute & Chronic):** Carboplatin is an anti-cancer drug used to treat ovarian cancer. May cause irritation to eyes, skin, and respiratory system. May produce allergic response and effects the kidneys, blood, and gastrointestinal and central nervous systems. Carboplatin is mutagenic and teratogenic. It is a potential carcinogen and reproductive effector.

**Carcinogenicity:** NTP? NO IARC Monographs? NO OSHA Regulated? No

**Signs & Symptoms of Exposure:** Carboplatin is a potent anti-cancer drug and is highly toxic upon acute exposures. Nausea and vomiting may occur. Allergic reactions may cause facial edema, flushing, wheezing/difficulty in breathing, tachycardia, and hypotension are possible. May cause ringing in the ears. Irritation to eyes, skin and respiratory system may occur. Chronic exposures may cause kidney disorders, peripheral neuropathy, bone marrow depression, and moderate, reversible blood changes.

**Medical Conditions Generally Aggravated by Exposure:** Kidney disease, hearing disorders, neurological and blood diseases may be aggravated due to exposure to Carboplatin.

**BVL Hazard Category:** 4

**BVL Occupational Exposure limit (OEL):** 0.9 ug/m<sup>3</sup>

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#### **Section IV - FIRST AID MEASURES**

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**Eye Exposure:** Flush eyes with large volumes of water for 15 minutes or more. Seek treatment from a physician.

**Skin Exposure:** Wash skin with cool, soapy water. Remove contaminated clothing.

**Ingestion:** If ingestion occurs, flush mouth with water and seek medical attention immediately.

If person is conscious, induce vomiting; never induce vomiting on an unconscious person.

**Inhalation:** If difficulty breathing, administer oxygen. Seek medical attention immediately.

If necessary, provide artificial respiration.

Overdose should be treated symptomatically.

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#### **Section V - FIRE AND EXPLOSION HAZARD DATA**

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**Flash Point (Method Used):** Not applicable      **LEL:** Not Applicable      **UEL:** Not Applicable

**Flammable Limits:** Not applicable

**Extinguishing Media:** Use water or multi-purpose ABC extinguisher

**Special Fire Fighting Procedures:** As with all fires, evacuate personnel to a safe area. Fire fighters must wear self-contained breathing apparatus to avoid inhalation of smoke. Product is not expected to present a fire hazard concern.

**Unusual Fire/Explosion Hazards:** None

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#### **Section VI - ACCIDENTAL RELEASE INFORMATION**

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**Release to Land:** Wet Carboplatin with water and wipe up with absorbent materials. Prevent contact with sewers and waterways. Wash area with soap and water. Wear personal protective equipment.

**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.

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#### **Section VII - PRECAUTIONS FOR SAFE HANDLING AND USE**

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**Steps to be taken in case material is released or spilled:** See Section VI above. Wear all necessary protective equipment including nitrile or latex gloves, protective clothing, safety glasses, and an air-purifying respirator with HEPA (P100) cartridges. Large spills may require the use of protective coveralls, boots, double gloves and SCBAs.

**Waste Disposal Method:** Dispose of according to local, state, and federal guidelines. Incineration at a licensed facility is recommended.

**Precautions to be taken in handling and storing:** Store at room temperature (15-25°C).  
Do not refrigerate. Protect from light.

**Other Precautions:** Follow the recommended guidelines on the safe handling of cytotoxic products (see Section XVI). An interaction occurs between carboplatin and aluminum metal, resulting in precipitate formation and loss of drug potency. Only administration equipment such as needles and syringes that contain no aluminum should be used for this drug.

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## Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

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**Respiratory Protection:** Under normal use, respirators should not be required if adequate ventilation is available. If dust generation is likely, air-purifying respirators with HEPA cartridge (P100) must be worn. For large spill emergencies, self-contained breathing apparatus (SCBA) may be required. Personnel wearing respirators should be fit tested and approved for respirator use under the OSHA Respiratory Protection Standard, 29 CFR 1910.134.

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

**Protective Gloves:** Nitrile or latex

**Eye Protection:** Safety glasses or goggles

**Other Protective Clothing or Equipment:** Lab coat

**Work/Hygienic Practices:** Wash hands following use. No eating, drinking, or smoking when handling this product.

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## Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

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**Physical State:** Solid

**Appearance and Odor:** White odorless powder

**Boiling Point:** Not applicable

**Vapor Pressure:** Not applicable

**Vapor Density:** Not applicable

**Specific Gravity:** Not applicable

**Melting Point:** 235 °C

**Evaporation Rate:** Not applicable

**Solubility in Water:** Soluble

**pH:** 5.0 – 7.0

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## Section X - STABILITY AND REACTIVITY DATA

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**Stability:** Stable

**Incompatibility (Materials to Avoid):** Aluminum metal.

**Hazardous Decomposition or Byproducts:** Decomposition products of this compound may include potentially hazardous byproducts of nitrogen oxides, carbon monoxide, and carbon oxide.

**Hazardous Polymerization:** Will not occur

**Conditions to Avoid:** Avoid contact with oxidizers and water reactive materials.

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## Section XI - TOXICOLOGICAL INFORMATION

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For Carboplatin: RTECS # TP2300000

LD<sub>50</sub> oral, rat = 343 mg/kg

LD<sub>50</sub> subcutaneous, rat = 72 mg/kg

LD<sub>50</sub> intravenous, rat = 61 mg/kg

LD<sub>50</sub> intravenous, mouse = 90 mg/kg

LD<sub>50</sub> intraperitoneal, mouse = 118 mg/kg

LD<sub>50</sub> intravenous, dog = 31 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 for Occupational Safety and Health (NIOSH) Registry of Toxic Effects of Chemical Substances (RTECS).

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## **Section XII - ENVIRONMENTAL IMPACT INFORMATION**

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Information is currently not available on the environmental impact of Carboplatin. Handle in a manner that prevents spills or releases to the environment.

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## **Section XIII - DISPOSAL INFORMATION**

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Carboplatin should be disposed of in accordance with national, state, local, or applicable regulations. Incineration at an approved, permitted facility is recommended.

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## **Section XIV - TRANSPORTATION INFORMATION**

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Carboplatin 10 mg/mL is not a DOT Hazardous Material.  
Carboplatin is not a Marine Pollutant.

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## **Section XV - REGULATORY INFORMATION**

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SARA 313 listed?: No

CERCLA listed?: No

RCRA listed?: No

TSCA listed: No

Carboplatin is subject to California Proposition 65 carcinogen warning and release requirements Code D.

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## **Section XVI - OTHER DATA**

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1. Use of this product should be through or under the direction of a physician.  
This MSDS does not address the therapeutic use of this material
2. Persons administering this drug to patients must be careful to avoid needle sticks to syringes and other sharps used in the administration. All needle sticks must be reported to your company Management.
3. BVL Hazard Category Definitions (internal hazard ranking used by Ben Venue Laboratories):  
1 = Low Toxicity  
2.= Moderate Toxicity  
3 = Potent or Toxic  
4 = Highly Potent or Toxic  
5 = Extremely Potent or Toxic

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