



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 10 mg/mL; 5, 15, 45 and 60 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
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Section II - HAZARDOUS INGREDIENTS/COMPOSITION INFORMATION

<u>Component</u>	<u>%</u>	<u>CAS#</u>	<u>OSHA PEL</u>	<u>ACGIH TLV</u>	<u>Other Limits Recommended</u>
Carboplatin	1.0	41575-94-4	2 ug/m ³ (as Platinum)	2 ug/m ³ (as Platinum)	0.9 ug/m ³ (BVL OEL)
Water for Injection	99	7732-18-5	NONE	NONE	NONE

Carboplatin is a sterile injectable liquid drug provided in 5, 15, 45 and 60 mL 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/m³

Section IV - FIRST AID MEASURES

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.

Section V - FIRE AND EXPLOSION HAZARD DATA

Flash Point (Method Used): > 200° **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

Section VI - ACCIDENTAL RELEASE INFORMATION

Release to Land: Absorb Carboplatin with water absorbent wipes or towels. Prevent contact with sewers and waterways. Wash area with soap and water. Wear personal protective equipment.

Release to Air: If aerosols are generated, reduce exposures by ventilating and preventing the generation of aerosols. 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 VII - PRECAUTIONS FOR SAFE HANDLING AND USE

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.

Section VIII - CONTROL MEASURES AND PERSONAL PROTECTIVE EQUIPMENT

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.

Section IX - PHYSICAL/CHEMICAL CHARACTERISTICS

Physical State: Liquid

Appearance and Odor: Clear, colorless, odorless

Boiling Point: Approximate to water

Vapor Pressure: Approximate to water

Vapor Density: Approximate to water

Specific Gravity: Approximate to water

Melting Point: Not applicable

Evaporation Rate: Approximate to water

Solubility in Water: Soluble

pH: 5.0 – 7.0

Section X - STABILITY AND REACTIVITY DATA

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.

Section XI - TOXICOLOGICAL INFORMATION

For Carboplatin: RTECS # TP2300000

LD₅₀ oral, rat = 343 mg/kg

LD₅₀ subcutaneous, rat = 72 mg/kg

LD₅₀ intravenous, rat = 61 mg/kg

LD₅₀ intravenous, mouse = 90 mg/kg

LD₅₀ intraperitoneal, mouse = 118 mg/kg

LD₅₀ 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).

Section XII - ENVIRONMENTAL IMPACT INFORMATION

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

Section XIII - DISPOSAL INFORMATION

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

Section XIV - TRANSPORTATION INFORMATION

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

Section XV - REGULATORY INFORMATION

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.

Section XVI - OTHER DATA

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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