



Bristol-Myers Squibb Company

MATERIAL SAFETY DATA SHEET

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

BRISTOL-MYERS SQUIBB, WORLDWIDE MEDICINES GROUP

December 7, 2000

P.O. BOX 191

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MSDS revised to change telephone numbers.

Product Identification Paraplatin AQ (carboplatin injection 10mg/ml)

Chemical Name: Platinum, diammine(1,1-cyclobutane-dicarboxylato(2-)-0,0')-, (SP-4-2)

Synonym: Carboplatin Injection; BMJ 26575 Injection; NSC 241240

How Supplied: Vials containing clear liquid (50, 150, or 450 mg carboplatin/vial, as labeled).

Product Use: Paraplatin AQ contains carboplatin, and is used to treat certain neoplastic diseases.

Chemical Family: Heavy metal complex

Molecular Formula: C₆H₁₂N₂O₄Pt

CAS NUMBER: 41575-94-4

EMERGENCY CONTACTS:

Transportation: CHEMTREC (800)424-9300. For all international transportation emergencies call Chemtrec at (703) 527-3887, collect call accepted.

EMERGENCY OVERVIEW: Paraplatin AQ is an aqueous liquid which is packaged in vials. This formulation contains carboplatin, a potent cytotoxic drug. Carboplatin is toxic after acute injection. It is a mutagen and potential carcinogen. It was embryotoxic and teratogenic in rats.

2. COMPOSITION/ INFORMATION ON INGREDIENTS

COMPONENTS	HAZARDOUS (Y/N)	CONCENTRATION (wt %)	CAS NUMBER	EXPOSURE GUIDELINE
Carboplatin	Y	1	41575-94-4	2 ug/m ³ (for platinum) (1)
Water for injection	N	>1	7732-18-5	none

1 OSHA PEL = Occupational Safety and Health Administration - Permissible Exposure Limit

3. HEALTH HAZARDS IDENTIFICATION

EFFECTS OF OVEREXPOSURE

Routes of Entry:

1. Inhalation: Under normal conditions, exposure to this material by inhalation would not be expected to occur. However, in a situation where the liquid would be aerosolized there may be potential for inhalation. The extent of systemic absorption of carboplatin after inhalation is unknown.

2. Skin Contact: Under normal conditions, this product is contained within vials and skin contact would not be expected to occur. Exposure to carboplatin may occur via skin contact if the vials break or spill and if gloves and protective clothing are not worn. The extent of systemic absorption of carboplatin after skin contact is not known.



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HEALTH HAZARDS IDENTIFICATION (CONTINUED)

3. Ingestion: Ingestion of large quantities of this material in an occupational setting would not be expected to occur. Ingestion of trace amount of the material might occur if vials are broken or spilled, if material contacts hands and if hands are not washed prior to eating, drinking, or smoking. The extent of systemic absorption of carboplatin from the gastrointestinal tract is not known.

Acute

Ingestion: Paraplatin AQ contains carboplatin, a potent cytotoxic drug. Carboplatin is toxic after acute ingestion.

Inhalation: There is no information concerning the potential of this material to produce symptoms after inhalation. Transient bronchial irritation may occur.

Skin Contact:

a. Toxic: There is no information concerning the potential of this material to produce symptoms after skin contact.

b. Irritation: This material presents a rare potential for skin irritation.

c. Sensitization: This material may produce a possible rash upon contact.

Eye Contact: This material may cause conjunctivitis.

Other: Paraplatin AQ is intended for intravenous injection under the supervision of physicians experienced in cancer chemotherapy. Carboplatin is toxic after acute systemic injection. Nausea and vomiting occur in almost all patients receiving this drug. Anaphylactoid reactions, consisting principally of rash, and, rarely, wheezing or respiratory difficulty, and hypotension, have occurred in 2% of the patients receiving the drug.

Chronic: Carboplatin is a potent cytotoxic drug that is administered intravenously. Side effects reported in persons treated with therapeutic doses of this drug include dose-related: generally reversible hematologic (blood) effects; reversible hepatic toxicity; reversible kidney abnormalities and electrolyte loss; ototoxicity (e.g. ringing of the ears and/or hearing loss); and peripheral neuropathy. Non-dose-dependent adverse effects include: nausea and vomiting; and anaphylactoid reactions. Carboplatin is a mutagen and a possible carcinogen.

Exposure Guideline Summary: See Composition.

Carcinogen Lists IARC: No NTP: No OSHA: No

Target Organs: The kidneys, nervous system, hematopoietic system, and gastrointestinal system are the major target organs. Other organ systems which undergo rapid cellular division may also be targets after systemic exposure.

Medical Conditions Aggravated by Exposure: Therapeutic doses of this material may aggravate kidney disease, hearing disorders, neurological diseases, or anemia or other forms of bone marrow suppression.

Medical Surveillance Recommendation: A pre-placement physical examination and history (noting any risk factors) for employees with potential exposure to Paraplatin AQ is recommended. A complete blood count, including differential,



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HEALTH HAZARDS IDENTIFICATION (CONTINUED)

blood tests for renal function and lung function tests may be taken to provide a baseline. Periodic follow-up examinations should be given in accordance with institutional policy, overseen by a physician thoroughly knowledgeable about both the toxicity of the substance and the extent of work place exposure. A permanent registry of all staff who routinely prepare or administer Paraplatin AQ should be considered.

Staff members who are pregnant, are breast-feeding, or who are concerned with other reproductive issues should be encouraged to consult with the occupational health physician monitoring workers' health.

FOR MORE INFORMATION REFER TO SECTION 11: TOXICOLOGICAL INFORMATION

4. FIRST AID MEASURES

Ingestion: Seek medical attention immediately. Induction of vomiting should be considered for significant ingestion if person is conscious and not experiencing convulsions. Never give anything by mouth to an unconscious person.

Inhalation: Remove exposed person to fresh air. If person is not breathing give artificial respiration. If breathing is difficult administer oxygen. Get medical attention.

Skin Contact: Remove contaminated clothing. Flush with water for 15 minutes.

Eye Contact: Hold eyelids apart and flush with running water for at least 15 minutes. Get medical attention immediately.

Note to physicians: Product contains a cytotoxic antineoplastic drug.

5. FIRE FIGHTING MEASURES

Flash point: Not determined.

Autoignition Temperature: Not determined.

Flammability limits:

LEL: Not determined

UEL: Not determined

Combustibility of Dusts: Not applicable.

Extinguishing Media: Unlikely to burn in vial. In case of fire, flood with water.

Firefighting Instructions: Firefighters should wear self contained breathing apparatus, flame and chemical resistant clothing, boots and gloves. Evacuate personnel to upwind direction, remove unneeded material and cool container(s) with water from a maximum distance.

Hazardous Combustion Products: CO, CO_x, NO_x, and possibly other compounds with carcinogenic potential.

Unusual Hazards: Product contains a cytotoxic anticancer drug. Avoid inhalation, ingestion, skin and eye contact. Decontaminate protective clothing and equipment after use.



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6. ACCIDENTAL RELEASE MEASURES

Spill/Clean-up: Small spills -- wipe liquids with absorbent gauze pads. Clean using detergent and water.

Large spills -- cover liquid with absorbent sheets, spill-control pads or pillows. Clean using detergents and water.

Treat product and contaminated materials as hazardous material. Incineration is recommended.

7. HANDLING AND STORAGE

Handling Precautions: Do not break vials or spill contents. Avoid inhalation, ingestion, skin and eye contact. See relevant guidance for handling cytotoxic materials.

Container Requirements: Do not allow Paraplatin AQ to contact aluminum. Aluminum reacts with formulated Paraplatin AQ, causing precipitate formation and a loss of potency.

Storage Conditions: Should be stored at room temperature (15-25 degrees C). Do not refrigerate. Protect from light.

8. EXPOSURE CONTROLS AND PERSONAL PROTECTION

Ventilation Requirements: Keep airborne concentrations below exposure guidelines by enclosure of processes or local exhaust ventilation, as required.

Respiratory Protection: When engineering controls are not sufficient to control exposure, or if BSC is not available, wear approved respiratory protection to control employee exposure; self-contained breathing apparatus should be available for emergency use.

Eye Protection: Wear chemical safety goggles (ANSI Z87.1).

Protective Gloves: Wear disposable surgical latex gloves rather than polyvinyl chloride (PVC) gloves. Gloves should be changed regularly and removed immediately after overt contamination. Double gloving is recommended for cleaning up spills.

Special Clothing: Wear impervious disposable coveralls with closed front, long sleeves and elastic cuffs, and boots to protect from dusts, splashes, or sprays. Remove disposable clothing prior to leaving the work area.

Hygiene: Wash hands, forearms, and face thoroughly after handling compounds and before eating, smoking, using lavatory, and at the end of day.

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance/Physical State/Color: Clear aqueous liquid which is packaged in vials.

Boiling point: Approx. 100 degrees C.

Evaporation rate: approx. the same as water

Flash point: not determined



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PHYSICAL AND CHEMICAL PROPERTIES (CONTINUED)

Freezing point: approx. 0 degrees C

Melting point: not applicable

Octanol/water partition coefficient: not determined

Odor (threshold): unknown

pH: 5-7 (1% solution)

Solubility in water: miscible

Specific gravity: approx. the same as water

Vapor density: approx. the same as water

Vapor Pressure: approx. the same as water

Viscosity: approx. the same as water

10. STABILITY AND REACTIVITY

Stability: When stored at room temperature (15-25 degrees C) in original container and protected from light, material is stable to expiration date shown on product label.

Incompatibilities: No known hazardous incompatibilities. An unusual incompatibility is the formation of a platinum precipitate when Paraplatin AQ comes in contact with aluminum.

Conditions of Reactivity: No information.

Hazardous Decomposition Products: CO, CO_x, NO_x, and possibly other compounds with carcinogenic potential.

Hazardous Polymerization: Will not occur in original container to expiration date.

Explosion data relative to mechanical impact: Not expected to be a mechanical explosion hazard.

Explosion data relative to static discharge: Not expected to be a dust explosion hazard.

11. TOXICOLOGICAL INFORMATION (for carboplatin)

RTECS NUMBER (U.S.): TP2300000

ACUTE

LD 50:

Acute oral LD50 (rat) = 343 mg/kg;

Acute iv LD50 (rat) = 61 mg/kg;

Acute iv LD50 (mouse) = 89.36 mg/kg;

Acute iv LD50 (dog) > 31.2 mg/kg;

Acute ip LD50 (mouse) = 150 mg/kg;

Acute sc LD50 (rat) = 72 mg/kg;

LC 50: Not tested



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TOXICOLOGICAL INFORMATION (for carboplatin) (CONTINUED)

CHRONIC

Carcinogenicity: The carcinogenic potential of carboplatin has not been studied. Compounds with similar mechanisms of action and mutagenicity profiles have been reported to be carcinogenic. Carboplatin should be considered a potential carcinogen in humans.

Mutagenicity: Carboplatin was positive in a battery of genetic toxicity tests. It has been shown to be mutagenic in bacteria and has produced chromosomal aberrations in animals cells in culture.

Teratogenicity: Carboplatin may cause fetal harm when administered to pregnant women. Carboplatin has been shown to be teratogenic and embryotoxic in rats.

Reproductive Effects: The effects of carboplatin on fertility have not been determined.

Toxicological synergistic products: The renal effects of nephrotoxic compounds may be potentiated by Carboplatin.

12. ECOLOGICAL INFORMATION

Ecotoxicological Information: Not determined.

Chemical Fate Information: Not determined.

13. DISPOSAL CONSIDERATIONS

Disposal: Dispose of in accordance with national, state, local or applicable country regulations. Treat products and contaminated materials as hazardous material. Incineration at an approved facility is recommended.

14. TRANSPORT INFORMATION

DOMESTIC

Hazard Class (UN NUMBER): not regulated by D.O.T.

Proper shipping name: not applicable

Label requirements: not applicable

Placard requirements: not applicable

Limited Quantity Exemption: not applicable

INTERNATIONAL

Hazard Class (UN NUMBER or PIN NUMBER): not regulated

Proper shipping name: not applicable

Label requirements: not applicable

Placard requirements: not applicable

Limited Quantity Exemption: not applicable

15. REGULATORY/STATUTORY INFORMATION -- not meant to be all inclusive

U.S. Federal: None noted

International: None noted

EC Labeling: None noted



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16. OTHER INFORMATION

Therapeutic agents are intended for use under direction of a physician and/or under the conditions of use described on the label. As a general precaution, personnel who handle drug substances should avoid contact (ingestion, inhalation, skin and eye contact) with these substances.

This material safety data sheet is intended for use by personnel who handle this material as part of their job responsibilities. It does not address the therapeutic use of this material. Information concerning the therapeutic use of this drug substance should be obtained from formulated product package inserts and other appropriate references.

Federal law prohibits dispensing without prescription. See package insert for recommended medical use. See OSHA Instruction PUB 8-1.1 for additional work practice guidelines for handling this material. Copies are available from OSHA Room N3651, 200 Constitution Ave., NW, Washington, DC 20210.

The information contained in this MSDS is believed to be accurate and represents the best information available at the time of preparation. However, we make no warranty, express or implied, with respect to such information, and we assume no liability from its use.