usp

SAFETY DATA SHEET

1. Identification

Product identifier Carboplatin

Other means of identification

 Catalog number
 1096407

 CAS number
 41575-94-4

Chemical name cis-Diammine(1,1-cyclobutanedicarboxylato)platinum

Recommended use Specified quality tests and assay use only.

Recommended restrictions None known.

Manufacturer/Importer/Supplier/Distributor information

Manufacturer

Company nameU. S. Pharmacopeia **Address**12601 Twinbrook Parkway

Rockville MD 20852-1790

United States

Telephone RS Technical Services 301-816-8129

Website www.usp.org
E-mail RSTECH@usp.org

Emergency phone number CHEMTREC within US & 1-800-424-9300

Canada

CHEMTREC outside US & +1 703-527-3887

Canada

2. Hazard(s) identification

Physical hazards Not classified.

Health hazards Acute toxicity, oral Category 4

Sensitization, respiratory

Sensitization, skin

Germ cell mutagenicity

Category 1B

Carcinogenicity

Category 1

Reproductive toxicity

Specific target organ toxicity, repeated

Category 1

Category 1

Category 1

exposure

Environmental hazards Not classified.

OSHA defined hazards Not classified.

Label elements



Signal word Dange

Hazard statement Harmful if swallowed. May cause an allergic skin reaction. May cause allergy or asthma

symptoms or breathing difficulties if inhaled. May cause genetic defects. May cause cancer. May damage fertility or the unborn child. Causes damage to organs () through prolonged or repeated

exposure.

Material name: Carboplatin USP SDS US

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Precautionary statement

Prevention Obtain special instructions before use. Do not handle until all safety precautions have been read

and understood. Do not breathe dust/fume/gas/mist/vapors/spray. Wash thoroughly after handling. Wear protective gloves/protective clothing/eye protection/face protection. Contaminated work clothing must not be allowed out of the workplace. In case of inadequate ventilation wear

respiratory protection.

Response If swallowed: Call a poison center/doctor if you feel unwell. Rinse mouth. If on skin: Wash with

plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse. If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a poison center/doctor. If

exposed or concerned: Get medical advice/attention.

Storage Store locked up.

Disposal Dispose of contents/container in accordance with local/regional/national/international regulations.

Hazard(s) not otherwise

classified (HNOC)

None known.

Supplemental information Potent pharmacologically active material.

3. Composition/information on ingredients

Substance

Chemical name	Common name and synonyms	CAS number	%
Carboplatin		41575-94-4	100

4. First-aid measures

Inhalation Move to fresh air. Call a physician if symptoms develop or persist.

Skin contact Rinse skin with water/shower. Get medical attention if irritation develops and persists.

Eye contact Rinse with water. Get medical attention if irritation develops and persists.

Ingestion Rinse mouth. If ingestion of a large amount does occur, call a poison control center immediately.

Most important

symptoms/effects, acute and

delayed

Bone marrow suppression. Potent pharmacologically active material. Occupational exposure to small amounts may cause physiological effects.

Indication of immediate medical attention and special

treatment needed
General information

Provide general supportive measures and treat symptomatically.

Remove from exposure. Remove contaminated clothing. For treatment advice, seek guidance from an occupational health physician or other licensed health-care provider familiar with workplace chemical exposures. In the United States, the national poison control center phone number is 1-800-222-1222. If person is not breathing, give artificial respiration. If breathing is difficult, give oxygen if available. Persons developing serious hypersensitivity (anaphylactic) reactions must receive immediate medical attention.

5. Fire-fighting measures

Suitable extinguishing media Water. Foam. Dry chemical or CO2. Use fire-extinguishing media appropriate for surrounding

materials.

Unsuitable extinguishing

media

None known.

Specific hazards arising from

No unusual fire or explosion hazards noted.

Special protective equipment and precautions for firefighters

Wear suitable protective equipment.

Fire fighting

the chemical

equipment/instructions

Use water spray to cool unopened containers. As with all fires, evacuate personnel to a safe area.

Firefighters should use self-contained breathing equipment and protective clothing.

Specific methodsUse standard firefighting procedures and consider the hazards of other involved materials.

General fire hazards No unusual fire or explosion hazards noted.

6. Accidental release measures

Personal precautions, protective equipment and emergency procedures Keep unnecessary personnel away. Wear appropriate personal protective equipment. Avoid inhalation of dust from the spilled material. Do not touch damaged containers or spilled material unless wearing appropriate protective clothing. Ensure adequate ventilation. For personal protection, see section 8 of the SDS.

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Methods and materials for containment and cleaning up

For waste disposal, see section 13 of the SDS. Avoid the generation of dusts during clean-up. Sweep up or vacuum up spillage and collect in suitable container for disposal. Clean surface thoroughly to remove residual contamination.

Avoid discharge into drains, water courses or onto the ground.

Environmental precautions
7. Handling and storage

Precautions for safe handling As a general rule, w

As a general rule, when handling USP Reference Standards, avoid all contact and inhalation of dust, mists, and/or vapors associated with the material. Clean equipment and work surfaces with suitable detergent or solvent after use. After removing gloves, wash hands and other exposed skin thoroughly. Select and use containment devices and personal protective equipment based on a risk assessment of material potency and exposure potential.

Conditions for safe storage, including any incompatibilities

Store in tight container as defined in the USP-NF. This material should be handled and stored per label instructions to ensure product integrity.

8. Exposure controls/personal protection

Occupational exposure limits

The following constituents are the only constituents of the product which have a PEL, TLV or other recommended exposure limit. At this time, the other constituents have no known exposure limits.

Exposure limit values

Industrial Use Material	Туре	Value	
Carboplatin (CAS 41575-94-4)	TWA	0.002 mg/m3	

No biological exposure limits noted for the ingredient(s).

Biological limit values

Appropriate engineering

controls

No open handling. For laboratory operations, use approved ventilation or containment system (biological safety cabinet, ventilated balance enclosure, glovebox). Control exposures to below the occupational exposure level (if available). Select and use containment devices and personal protective equipment based on a risk assessment of exposure potential. Cover all containers for

solutions and slurries while being transferred.

Individual protection measures, such as personal protective equipment

Eye/face protection Wear safety glasses with side shields, chemical splash goggles, or full face shield, if necessary.

Base the choice of protection on the job activity and potential for contact with eyes or face. An

emergency eye wash station should be available.

Skin protection

Hand protection Consider double gloves. Wear nitrile or other impervious gloves if skin contact is possible. When

the material is dissolved or suspended in an organic solvent, wear gloves that provide protection

against the solvent.

Other Train employees in proper gowning and degowning practices. Wear disposable lab coat,

disposable sleeve covers and two pair of gloves as appropriate for the task. Base the choice of skin protection on the job activity, potential for skin contact and solvents and reagents in use. Do

not wear protective garments in common areas (e.g., cafeterias) or out-of-doors.

Respiratory protection Use a powered air-purifying respirator (PAPR) with HEPA filters, disposable outerware and head

cover for spill cleanup. Choose respiratory protection appropriate to the task and the level of

existing engineering controls.

Thermal hazards Wear appropriate thermal protective clothing, when necessary.

General hygiene considerations

Pharmacological effects may be seen with occupational exposure. Handling practices in this SDS are recommendations for laboratory use of reference standards. Procedures for any other uses or

quantities should be determined after an appropriate assessment.

9. Physical and chemical properties

Appearance Appearance descriptions are general information and not specific to any USP lot.

Physical state Solid.
Form Powder.
Color White.

Odor Odorless.

Odor threshold Not available.

Physical state Solid.
Powder.
White.

Odorless.

Odorless.

Not available.

Melting point/freezing point Not available.

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Initial boiling point and boiling

range

Not available.

Flash point Not available.

Evaporation rate Not available.

Flammability (solid, gas) Not available.

Upper/lower flammability or explosive limits

Flammability limit - lower

(%)

Not available.

Flammability limit - upper

(%)

Not available.

Explosive limit - lower (%) Not available.

Explosive limit - upper (%) Not available.

Vapor pressure Not available.

Vapor density > 1

Relative density Not available.

Solubility(ies)

Solubility (water)Soluble.Auto-ignition temperatureNot available.Decomposition temperatureNot available.ViscosityNot available.

Other information

Chemical familyPlatinum analog.Molecular formulaC6-H12-N2-O4-PtMolecular weight371.25 g/molpH in aqueous solution5 - 7 (Solution: 1%)

10. Stability and reactivity

Reactivity The product is stable and non-reactive under normal conditions of use, storage and transport.

Chemical stability Material is stable under normal conditions.

Possibility of hazardous

reactions

No dangerous reaction known under conditions of normal use.

Conditions to avoid Contact with incompatible materials.

Incompatible materials Strong oxidizing agents. Aluminum.

Hazardous decomposition

products

NOx. Pt. Irritating and/or toxic fumes or gases. Emits toxic fumes under fire conditions.

11. Toxicological information

Information on likely routes of exposure

Inhalation May cause allergy or asthma symptoms or breathing difficulties if inhaled.

Skin contact May cause an allergic skin reaction.

Eye contact Knowledge about health hazard is incomplete.

Ingestion Harmful if swallowed.

Symptoms related to the physical, chemical and toxicological characteristics

Platinum containing compounds: Ringing in ears. Hearing problems. Tiredness. Weakness. Gastrointestinal disturbances. Numbness, pain, tingling, or weakness in hands or feet. Fever.

Chills. Cough. Bleeding or bruising. Rash. Dizziness. Difficulty breathing.

Information on toxicological effects

Acute toxicity Harmful if swallowed.

Product Species Test Results

Carboplatin (CAS 41575-94-4)

Oral

LD50 Rat 343 mg/kg

Skin corrosion/irritation Knowledge about health hazard is incomplete.

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Serious eye damage/eye

irritation

Knowledge about health hazard is incomplete.

Respiratory or skin sensitization

Respiratory sensitization May cause allergy or asthma symptoms or breathing difficulties if inhaled. As with other platinum

analogs, allergic and anaphylactoid reactions have been reported in literature.

Skin sensitization May cause an allergic skin reaction. Skin hypersensitivity reactions have been reported with

occupational exposure to platinum-containing compounds.

Germ cell mutagenicity May cause genetic defects.

Mutagenicity

Ames assay (Salmonella) Result: Inconclusive.

Chinese hamster ovary assay

Result: Positive.

Mouse lymphoma assay

Result: Positive.

Carcinogenicity May cause cancer. Secondary malignancies are potential delayed effects of many antineoplastic

agents, although it is not clear whether the effect is related to their mutagenic or

immunosuppressive action. The effect of dose and duration of therapy is also unknown, although

risk seems to increase with long-term use.

IARC Monographs. Overall Evaluation of Carcinogenicity

Not listed.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

US. National Toxicology Program (NTP) Report on Carcinogens

Not listed.

Reproductive toxicity

May damage fertility or the unborn child. Antineoplastic therapy can adversely affect male and

female fertility through gonadal suppression, resulting in the absence of menstruation or sperm.

The effects appear to be related to dose and length of therapy and may be irreversible.

Reproductivity

24 mg/kg/day Gestational study (6th to 9th day)

Result: Developmental abnormalities of the CNS,

musculoskeletal system, and body wall.

Species: Rat

30 - 60 mg/l Fertility study (carboplatin added to sperm

samples)

Result: Sperm membrane damage.

Species: Human

4 mg/kg/day Reproductive study

Result: Increased fetal mortality and decreased intrauterine

growth and skeletal bone formulation.

Species: Rat

Specific target organ toxicity -

single exposure

Knowledge about health hazard is incomplete.

Specific target organ toxicity -

repeated exposure

Causes damage to organs () through prolonged or repeated exposure.

Aspiration hazard Based on available data, the classification criteria are not met.

Further information Potent pharmacologically active material. Occupational exposure to small amounts may cause

physiological effects.

12. Ecological information

Ecotoxicity The product is not classified as environmentally hazardous. However, this does not exclude the

possibility that large or frequent spills can have a harmful or damaging effect on the environment.

Persistence and degradability No data is available on the degradability of this product.

Bioaccumulative potential No data available.

Mobility in soil No data available.

Other adverse effects No other adverse environmental effects (e.g. ozone depletion, photochemical ozone creation

potential, endocrine disruption, global warming potential) are expected from this component.

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13. Disposal considerations

Disposal instructions Dispose in accordance with all applicable regulations. Under RCRA, it is the responsibility of the

user of the product to determine, at the time of disposal, whether the product meets RCRA criteria

for hazardous waste.

Dispose in accordance with all applicable regulations. Local disposal regulations

Hazardous waste code The waste code should be assigned in discussion between the user, the producer and the waste

disposal company.

Waste from residues / unused

products

Empty containers or liners may retain some product residues. This material and its container must

be disposed of in a safe manner (see: Disposal instructions).

Since emptied containers may retain product residue, follow label warnings even after container is Contaminated packaging

emptied.

14. Transport information

DOT

Not regulated as dangerous goods.

IATA

Not regulated as dangerous goods.

Transport in bulk according to Annex II of MARPOL 73/78 and

the IBC Code

General information It is the shipper's responsibility to determine the correct transport classification at the time of

shipment.

Not applicable.

15. Regulatory information

This product is a "Hazardous Chemical" as defined by the OSHA Hazard Communication **US** federal regulations

Standard, 29 CFR 1910.1200.

Toxic Substances Control Act (TSCA)

TSCA Section 12(b) Export Notification (40 CFR 707, Subpt. D)

Not regulated.

CERCLA Hazardous Substance List (40 CFR 302.4)

Not listed.

SARA 304 Emergency release notification

Not regulated.

OSHA Specifically Regulated Substances (29 CFR 1910.1001-1053)

Not listed.

Superfund Amendments and Reauthorization Act of 1986 (SARA)

SARA 302 Extremely hazardous substance

Not listed.

SARA 311/312 Hazardous

chemical

Yes

Classified hazard

categories

Acute toxicity (any route of exposure) Respiratory or skin sensitization

Germ cell mutagenicity Carcinogenicity Reproductive toxicity

Specific target organ toxicity (single or repeated exposure)

SARA 313 (TRI reporting)

Not regulated.

Other federal regulations

Clean Air Act (CAA) Section 112 Hazardous Air Pollutants (HAPs) List

Not regulated.

Clean Air Act (CAA) Section 112(r) Accidental Release Prevention (40 CFR 68.130)

Not regulated.

Safe Drinking Water Act

(SDWA)

Not regulated.

WARNING: This product contains a chemical known to the State of California to cause birth **US** state regulations

defects or other reproductive harm.

Material name: Carboplatin USP SDS US

California Proposition 65

California Proposition 65 - CRT: Listed date/Developmental toxin

Carboplatin (CAS 41575-94-4) Listed: July 1, 1990

International Inventories

Country(s) or region	Inventory name	On inventory (yes/no)*
Australia	Australian Inventory of Chemical Substances (AICS)	No
Canada	Domestic Substances List (DSL)	No
Canada	Non-Domestic Substances List (NDSL)	No
China	Inventory of Existing Chemical Substances in China (IECSC)	No
Europe	European Inventory of Existing Commercial Chemical Substances (EINECS)	Yes
Europe	European List of Notified Chemical Substances (ELINCS)	No
Japan	Inventory of Existing and New Chemical Substances (ENCS)	No
Korea	Existing Chemicals List (ECL)	No
New Zealand	New Zealand Inventory	Yes
Philippines	Philippine Inventory of Chemicals and Chemical Substances (PICCS)	No
Taiwan	Taiwan Chemical Substance Inventory (TCSI)	Yes

^{*}A "Yes" indicates that all components of this product comply with the inventory requirements administered by the governing country(s)

A "No" indicates that one or more components of the product are not listed or exempt from listing on the inventory administered by the governing country(s).

16. Other information, including date of preparation or last revision

Issue date 07-14-2006 **Revision date** 12-14-2020

Version # 03

United States & Puerto Rico

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Toxic Substances Control Act (TSCA) Inventory

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herein.

Material name: Carboplatin usp sps us

No