

SDS Title: Carboplatin Injection	SDS Number: SDS-000001	Page Number: 1 of 8
Function: Regulatory Affairs	Effective Date: August 02, 2018	Version Number: 2.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Carboplatin Injection (10mg/mL)

Synonyms: platinum, diammine [1,1-cyclobutane-dicarboxylato(2-)-0,0']-,(SP-4-2)

1.2. Intended Use of the Product

Use of the Substance/Mixture: Pharmaceutucial, use only as directed. Refer to product insert for product information and usage instructions. Medical Treatment; Ovarian Carcinoma (Antineoplastic belonging to the group of medicines known as alkylating agents).

1.3. Name, Address, and Telephone of the Responsible Party

Company

Meitheal Pharmaceuticals, Inc.

8700 W. Bryn Mawr, Suite 600S

Chicago, IL 60631

224-443-4617

www.meithealpharma.com

1.4. Emergency Telephone Number

Emergency Number : 844-824-8426

SECTION 2: HAZARDS IDENTIFICATION

2.1. Classification of the Substance or Mixture

Resp. Sens. 1 H334

Skin Sens. 1 H317

Muta. 1B H340

Repr. 1B H360

Lact. H362

Full text of hazard classes and H-statements : see section 16

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US) :



GHS08

Signal Word (GHS-US) :

Danger

Hazard Statements (GHS-US) :

H317 - May cause an allergic skin reaction.

H334 - May cause an allergy or asthma symptoms or breathing difficulties if inhaled.

H340 - May cause genetic defects.

H360 - May damage fertility or the unborn child.

H362 - May cause harm to breast-fed children.

Precautionary Statements (GHS-US) :

P201 - Obtain special instructions before use.

P202 - Do not handle until all safety precautions have been read and understood.

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- P260 - Do not breathe vapors, mist, or spray.
- P263 - Avoid contact during pregnancy/while nursing.
- P264 - Wash hands, forearms, and other exposed areas thoroughly after handling.
- P270 - Do not eat, drink or smoke when using this product.
- P272 - Contaminated work clothing must not be allowed out of the workplace.
- P280 - Wear protective gloves, protective clothing, and eye protection.
- P284 - [In case of inadequate ventilation] wear respiratory protection.
- P302+P352 - If on skin: Wash with plenty of water.
- P304+P341 - If inhaled: If breathing is difficult, remove person to fresh air and keep comfortable for breathing.
- P308+P313 - If exposed or concerned: Get medical advice/attention.
- P321 - Specific treatment (see section 4 on this SDS).
- P333+P313 - If skin irritation or rash occurs: Get medical advice/attention.
- P342+P311 - If experiencing respiratory symptoms: Call a poison center or doctor.
- P363 - Wash contaminated clothing before reuse.
- P405 - Store locked up.
- P501 - Dispose of contents/container in accordance with local, regional, national, and international regulations.

2.3. Other Hazards

Exposure may aggravate pre-existing eye, skin, or respiratory conditions. Exposure may aggravate individuals with pre-existing skin, kidney, liver, and pulmonary disorders.

2.4. Unknown Acute Toxicity (GHS-US)

No data available

SECTION 3: COMPOSITION/INFORMATION ON INGREDIENTS

3.1. Substance

Not applicable

3.2. Mixture

Name	Product Identifier	%	GHS-US classification
Water	(CAS-No.) 7732-18-5	99	Not classified
Carboplatin	(CAS-No.) 41575-94-4	1	Acute Tox. 4 (Oral), H302 Acute Tox. 4 (Dermal), H312 Acute Tox. 4 (Inhalation:dust,mist), H332 Resp. Sens. 1, H334 Skin Sens. 1, H317 Muta. 1B, H340 Lact., H362 Repr. 1B, H360

Full text of H-phrases: see section 16

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SECTION 4: FIRST AID MEASURES

4.1. Description of First-aid Measures

First-aid Measures General: Never give anything by mouth to an unconscious person. If you feel unwell, seek medical advice (show the label where possible).

First-aid Measures After Inhalation: When symptoms occur: go into open air and ventilate suspected area. Obtain medical attention if breathing difficulty persists.

First-aid Measures After Skin Contact: Remove contaminated clothing. Drench affected area with water for at least 15 minutes. Obtain medical attention if irritation/rash develops or persists.

First-aid Measures After Eye Contact: Remove contact lenses, if present and easy to do. Continue rinsing. Rinse cautiously with water for at least 15 minutes. Obtain medical attention.

First-aid Measures After Ingestion: Rinse mouth. Do NOT induce vomiting. Obtain medical attention.

4.2. Most Important Symptoms and Effects Both Acute and Delayed

Symptoms/Injuries: Please refer to the package insert for more detailed information. Skin sensitization. May cause allergy or asthma symptoms or breathing difficulties if inhaled. May cause genetic defects. May damage fertility. May damage the unborn child. May cause harm to breast-fed children.

Symptoms/Injuries After Inhalation: Exposure may produce cough, mucous secretions, shortness of breath, chest tightness or other symptoms indicative of an allergic/sensitization reaction.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: May cause genetic defects. May damage fertility or the unborn child. Overexposure may cause neuropathy, hearing loss, blindness, anemia, bone marrow depression, and other adverse effects. Symptoms of overexposure may include: anaphylaxis, fever, flu-like symptoms, nausea, chills, vomiting, labored breathing, weight loss, malaise, and other effects.

4.3. Indication of Any Immediate Medical Attention and Special Treatment Needed

If exposed or concerned, get medical advice and attention. If medical advice is needed, have product container or label at hand. In the event of accidental injection, immediately call a poison center or seek medical advice.

SECTION 5: FIRE-FIGHTING MEASURES

5.1. Extinguishing Media

Suitable Extinguishing Media: Water spray, fog, carbon dioxide (CO₂), alcohol-resistant foam, or dry chemical.

Unsuitable Extinguishing Media: Do not use a heavy water stream. Use of heavy stream of water may spread fire.

5.2. Special Hazards Arising From the Substance or Mixture

Fire Hazard: Not considered flammable but may burn at high temperatures.

Explosion Hazard: Product is not explosive.

Reactivity: Hazardous reactions will not occur under normal conditions.

5.3. Advice for Firefighters

Precautionary Measures Fire: Exercise caution when fighting any chemical fire.

Firefighting Instructions: Use water spray or fog for cooling exposed containers.

Protection During Firefighting: Do not enter fire area without proper protective equipment, including respiratory protection.

Hazardous Combustion Products: Nitrogen oxides. Carbon oxides (CO, CO₂). Sulfur oxides.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

General Measures: Do not breathe vapor, mist or spray. Do not get in eyes, on skin, or on clothing.

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6.1.1. For Non-Emergency Personnel

Protective Equipment: Use appropriate personal protective equipment (PPE).

Emergency Procedures: Evacuate unnecessary personnel.

6.1.2. For Emergency Personnel

Protective Equipment: Equip cleanup crew with proper protection.

Emergency Procedures: Upon arrival at the scene, a first responder is expected to recognize the presence of dangerous goods, protect oneself and the public, secure the area, and call for the assistance of trained personnel as soon as conditions permit. Ventilate area.

6.2. Environmental Precautions

Prevent entry to sewers and public waters.

6.3. Methods and Materials for Containment and Cleaning Up

For Containment: Contain any spills with dikes or absorbents to prevent migration and entry into sewers or streams.

Methods for Cleaning Up: Clean up spills immediately and dispose of waste safely. Transfer spilled material to a suitable container for disposal. Contact competent authorities after a spill.

6.4. Reference to Other Sections

See Section 8 for exposure controls and personal protection and Section 13 for disposal considerations.

SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

Additional Hazards When Processed: When heated to decomposition, emits toxic fumes.

Precautions for Safe Handling: Do not breathe vapor, mist, or sprays. Do not get in eyes, on skin, or on clothing. Avoid contact during pregnancy/while nursing. Obtain special instructions before use. Do not handle until all safety precautions have been read and understood. Wash hands and other exposed areas with mild soap and water before eating, drinking or smoking and when leaving work.

Hygiene Measures: Handle in accordance with good industrial hygiene and safety procedures.

7.2. Conditions for Safe Storage, Including Any Incompatibilities

Technical Measures: Comply with applicable regulations.

Storage Conditions: Keep container closed when not in use. Store in a dry, cool place. Store locked up/in a secure area.

Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials.

Incompatible Materials: Strong acids, strong bases, strong oxidizers.

7.3. Specific End Use(s)

Pharmaceutical, use only as directed. Refer to product insert for product information and usage instructions. Medical Treatment; Ovarian Carcinoma (Antineoplastic belonging to the group of medicines known as alkylating agents).

SECTION 8: EXPOSURE CONTROLS/PERSONAL PROTECTION

8.1. Control Parameters

For substances listed in section 3 that are not listed here, there are no established exposure limits from the manufacturer, supplier, importer, or the appropriate advisory agency including: ACGIH (TLV), AIHA (WEEL), NIOSH (REL), or OSHA (PEL).

8.2. Exposure Controls

Appropriate Engineering Controls : Suitable eye/body wash equipment should be available in the vicinity of any potential exposure. Ensure adequate ventilation, especially in confined areas. Ensure all national/local regulations are observed.

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Personal Protective Equipment : Gloves. Protective clothing. Protective goggles. Insufficient ventilation: wear respiratory protection.



Materials for Protective Clothing : Chemically resistant materials and fabrics.
 Hand Protection : Wear protective gloves.
 Eye and Face Protection : Chemical safety goggles.
 Skin and Body Protection : Wear suitable protective clothing.
 Respiratory Protection : If exposure limits are exceeded or irritation is experienced, approved respiratory protection should be worn. In case of inadequate ventilation, oxygen deficient atmosphere, or where exposure levels are not known wear approved respiratory protection.
 Consumer Exposure Controls : Avoid contact during pregnancy/while nursing.
 Other Information : When using, do not eat, drink or smoke.

SECTION 9: PHYSICAL AND CHEMICAL PROPERTIES

9.1. Information on Basic Physical and Chemical Properties

Physical State : Liquid
 Appearance : Clear, colorless to slightly yellow
 Odor : No data available
 Odor Threshold : No data available
 pH : 5 - 7
 Evaporation Rate : No data available
 Melting Point : No data available
 Freezing Point : No data available
 Boiling Point : No data available
 Flash Point : No data available
 Auto-ignition Temperature : No data available
 Decomposition Temperature : No data available
 Flammability (solid, gas) : Not applicable
 Vapor Pressure : No data available
 Relative Vapor Density at 20°C : No data available
 Relative Density : No data available
 Solubility : No data available
 Partition Coefficient: N-Octanol/Water : No data available
 Viscosity : No data available

9.2. Other Information No additional information available

SECTION 10: STABILITY AND REACTIVITY

10.1. Reactivity: Hazardous reactions will not occur under normal conditions.

10.2. Chemical Stability: Stable under recommended handling and storage conditions (see section 7).

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- 10.3. **Possibility of Hazardous Reactions:** Hazardous polymerization will not occur.
- 10.4. **Conditions to Avoid:** Direct sunlight, extremely high or low temperatures, and incompatible materials.
- 10.5. **Incompatible Materials:** Strong acids, strong bases, strong oxidizers.
- 10.6. **Hazardous Decomposition Products:** Nitrogen oxides. Sulfur oxides. Carbon oxides (CO, CO₂).

SECTION 11: TOXICOLOGICAL INFORMATION

11.1. Information on Toxicological Effects

Acute Toxicity: Not classified

Carboplatin (41575-94-4)	
LD50 Oral Rat	343 mg/kg
ATE (Dermal)	1,100.00 mg/kg body weight
ATE (Dust/Mist)	1.50 mg/l/4h

Skin Corrosion/Irritation: Not classified

pH: 5 - 7

Serious Eye Damage/Irritation: Not classified

pH: 5 - 7

Respiratory or Skin Sensitization: May cause an allergy or asthma symptoms or breathing difficulties if inhaled. May cause an allergic skin reaction.

Germ Cell Mutagenicity: May cause genetic defects.

Carcinogenicity: Not classified

Reproductive Toxicity: May damage fertility or the unborn child. May cause harm to breast-fed children. (This material or its emissions may appear in breast milk of nursing mothers.)

Specific Target Organ Toxicity (Single Exposure): Not classified

Specific Target Organ Toxicity (Repeated Exposure): Not classified

Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Exposure may produce cough, mucous secretions, shortness of breath, chest tightness or other symptoms indicative of an allergic/sensitization reaction.

Symptoms/Injuries After Skin Contact: May cause an allergic skin reaction.

Symptoms/Injuries After Eye Contact: May cause slight irritation to eyes.

Symptoms/Injuries After Ingestion: Ingestion may cause adverse effects.

Chronic Symptoms: May cause genetic defects. May damage fertility or the unborn child. Overexposure may cause neuropathy, hearing loss, blindness, anemia, bone marrow depression, and other adverse effects. Symptoms of overexposure may include: anaphylaxis, fever, flu-like symptoms, nausea, chills, vomiting, labored breathing, weight loss, malaise, and other effects.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

12.2. Persistence and Degradability

Carboplatin Injection (10mg/mL)	
Persistence and Degradability	Not established.

12.3. Bioaccumulative Potential

Carboplatin Injection (10mg/mL)	
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Bioaccumulative Potential	Not established.
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12.4. Mobility in Soil No additional information available

12.5. Other Adverse Effects

Other Information : Avoid release to the environment.

SECTION 13: DISPOSAL CONSIDERATIONS

13.1. Waste Treatment Methods

Waste Disposal Recommendations: Dispose of contents/container in accordance with local, regional, national, and international regulations.

Additional Information: Container may remain hazardous when empty. Continue to observe all precautions.

Ecology - Waste Materials: Avoid release to the environment.

SECTION 14: TRANSPORT INFORMATION

The shipping description(s) stated herein were prepared in accordance with certain assumptions at the time the SDS was authored, and can vary based on a number of variables that may or may not have been known at the time the SDS was issued.

14.1. In Accordance with DOT Not regulated for transport

14.2. In Accordance with IMDG Not regulated for transport

14.3. In Accordance with IATA Not regulated for transport

SECTION 15: REGULATORY INFORMATION

15.1. US Federal Regulations

Carboplatin Injection (10mg/mL)	
SARA Section 311/312 Hazard Classes	Health hazard - Respiratory or skin sensitization Health hazard - Germ cell mutagenicity Health hazard - Reproductive toxicity
Water (7732-18-5)	
Listed on the United States TSCA (Toxic Substances Control Act) inventory	

15.2. US State Regulations

Carboplatin (41575-94-4)	
U.S. - California - Proposition 65 - Developmental Toxicity	WARNING: This product contains chemicals known to the State of California to cause birth defects.

SECTION 16: OTHER INFORMATION, INCLUDING DATE OF PREPARATION OR LAST REVISION

Date of Preparation or Latest Revision : 08/02/2018
Other Information : This document has been prepared in accordance with the SDS requirements of the OSHA Hazard Communication Standard 29 CFR 1910.1200

GHS Full Text Phrases:

Acute Tox. 4 (Dermal)	Acute toxicity (dermal) Category 4
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Acute Tox. 4 (Inhalation:dust,mist)	Acute toxicity (inhalation:dust,mist) Category 4
Acute Tox. 4 (Oral)	Acute toxicity (oral) Category 4
Lact.	Reproductive toxicity (Lact.)
Muta. 1B	Germ cell mutagenicity Category 1B
Repr. 1B	Reproductive toxicity Category 1B
Resp. Sens. 1	Respiratory sensitization, Category 1
Skin Sens. 1	Skin sensitization, Category 1
H302	Harmful if swallowed
H312	Harmful in contact with skin
H317	May cause an allergic skin reaction
H332	Harmful if inhaled
H334	May cause an allergy or asthma symptoms or breathing difficulties if inhaled
H340	May cause genetic defects
H360	May damage fertility or the unborn child
H362	May cause harm to breast-fed children

This information is based on our current knowledge and is intended to describe the product for the purposes of health, safety and environmental requirements only. It should not therefore be construed as guaranteeing any specific property of the product.

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