

SDS Title: Oxaliplatin Injection	SDS Number: SDS-000002	Page Number: Page 1 of 7
Function: Regulatory Affairs	Effective Date: July 15, 2020	Version Number: 3.0

SECTION 1: IDENTIFICATION

1.1. Product Identifier

Product Form: Mixture

Product Name: Oxaliplatin Injection (5mg of Oxaliplatin/mL)

Synonyms: cis-[(1R,2R)-1,2-cyclohexanediamine-N,N'] [oxalato(2-)-O,O'] platinum.

1.2. Intended Use of the Product

Use of the Substance/Mixture: Pharmaceutical, use only as directed. Refer to product insert for product information and usage instructions. Antineoplastic. For professional use only.

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

Skin Sens. 1 H317

Carc. 2 H351

Repr. 1B H360

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

2.2. Label Elements

GHS-US Labeling

Hazard Pictograms (GHS-US)



Signal Word (GHS-US)

: Danger

Hazard Statements (GHS-US)

: H317 - May cause an allergic skin reaction.
H351 - Suspected of causing cancer.
H360 - May damage fertility or the unborn child.

Precautionary Statements (GHS-US)

: P201 - Obtain special instructions before use.
P202 - Do not handle until all safety precautions have been read and understood.
P261 - Avoid breathing vapors, mist, or spray.
P272 - Contaminated work clothing must not be allowed out of the workplace.
P280 - Wear protective gloves, protective clothing, and eye protection.
P302+P352 - If on skin: Wash with plenty of water.
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.



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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	99.5	Not classified
Oxaliplatin	(CAS-No.) 61825-94-3	0.5	Skin Irrit. 2, H315 Eye Irrit. 2A, H319 Skin Sens. 1, H317 Carc. 2, H351 Repr. 1B, H360 STOT SE 3, H335

Full text of H-phrases: see section 16

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. Suspected of causing cancer. May damage fertility. May damage the unborn child. Overexposure may cause or aggravate blood and lymphatic system(s) and disorders, immune system disorders, subcutaneous and tissue disorders, liver disorders, damage to the central nervous system, liver effects, and other adverse effects.

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

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

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



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

Chronic Symptoms: Suspected of causing cancer. May damage fertility or the unborn child.

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: Carbon oxides (CO, CO₂). May liberate toxic gases.

SECTION 6: ACCIDENTAL RELEASE MEASURES

6.1. Personal Precautions, Protective Equipment and Emergency Procedures

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

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.

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SECTION 7: HANDLING AND STORAGE

7.1. Precautions for Safe Handling

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

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. Keep/Store away from direct sunlight, extremely high or low temperatures and incompatible materials. Store locked up/in a secure area.

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. Antineoplastic. For professional use only.

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).

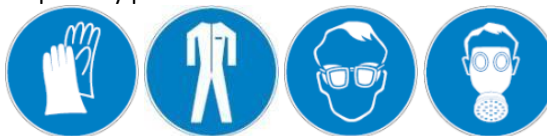
8.2. Exposure Controls

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.

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.

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



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Odor	: Odorless
Odor Threshold	: No data available
pH	: 4 - 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	: Slightly soluble in water (about 6mg/mL at 20 deg C); practically insoluble in dehydrated alcohol; very slightly soluble in methyl alcohol
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).
- 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:** Carbon oxides (CO, CO₂). Nitrogen oxides.

SECTION 11: TOXICOLOGICAL INFORMATION

- 11.1. Information on Toxicological Effects**
 - Acute Toxicity:** Not classified
 - Skin Corrosion/Irritation:** Not classified
 - pH:** 4 - 7
 - Serious Eye Damage/Irritation:** Not classified
 - pH:** 4 - 7
 - Respiratory or Skin Sensitization:** May cause an allergic skin reaction.
 - Germ Cell Mutagenicity:** Not classified
 - Carcinogenicity:** Suspected of causing cancer.
 - Reproductive Toxicity:** May damage fertility or the unborn child.
 - Specific Target Organ Toxicity (Single Exposure):** Not classified
 - Specific Target Organ Toxicity (Repeated Exposure):** Not classified



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Aspiration Hazard: Not classified

Symptoms/Injuries After Inhalation: Prolonged exposure may cause irritation.

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: Suspected of causing cancer. May damage fertility or the unborn child.

SECTION 12: ECOLOGICAL INFORMATION

12.1. Toxicity

Ecology - General : Not classified.

12.2. Persistence and Degradability

Oxaliplatin Injection (5mg of Oxaliplatin/mL)

Persistence and Degradability : Not established.

12.3. Bioaccumulative Potential

Oxaliplatin Injection (5mg of Oxaliplatin/mL)

Bioaccumulative Potential : Not established.

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

Oxaliplatin Injection (5mg of Oxaliplatin/mL)

SARA Section 311/312 Hazard Classes

Health hazard - Respiratory or skin sensitization
Health hazard - Carcinogenicity
Health hazard - Reproductive toxicity

Water (7732-18-5)



Meitheal Pharmaceuticals, Inc.

Safety Data Sheet

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Listed on the United States TSCA (Toxic Substances Control Act) inventory

15.2. US State Regulations Neither this product nor its chemical components appear on any US state lists, or its chemical components are not required to be disclosed

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

Date of Preparation or Latest Revision : 07/15/2020
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:

Carc. 2	Carcinogenicity Category 2
Eye Irrit. 2A	Serious eye damage/eye irritation Category 2A
Repr. 1B	Reproductive toxicity Category 1B
Skin Irrit. 2	Skin corrosion/irritation Category 2
Skin Sens. 1	Skin sensitization, Category 1
STOT SE 3	Specific target organ toxicity (single exposure) Category 3
H315	Causes skin irritation
H317	May cause an allergic skin reaction
H319	Causes serious eye irritation
H335	May cause respiratory irritation
H351	Suspected of causing cancer
H360	May damage fertility or the unborn child

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.