



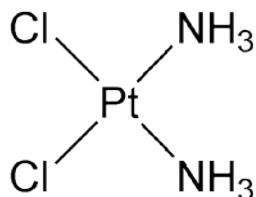
1. PRODUCT AND COMPANY INFORMATION

Distributed By: WG Critical Care, LLC.
120 Route 17 North
Suite 115
Paramus, NJ 07652 USA

Product Name: **Cisplatin for Injection, USP**

Active Ingredient Primary Component: Cisplatin

Structure:



Chemical Name: (1) Platinum, diamminedichloro-, (*SP-4-2*)-; (2) *cis*-Diamminedichloroplatinum.

Molecular Formula: $\text{Cl}_2\text{H}_6\text{N}_2\text{Pt}$

UNII Code: *UNII-Q20Q21Q62J*

CAS Number: *15663-27-1*

Chemical Family: Antineoplastic

Product Use: Pharmaceutical

Product Type: Prescription Drug

Container Information: Vials

Customer Service Phone Number: +1-888-493-0861

Emergency Phone Number: +1-866-562-4708 (ProPharma)

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2. HAZARDS IDENTIFICATION

2.1. Classification of the substance or mixture

Classification in accordance with the Regulation 1272/2008/EC (CLP) Acute toxicity, Oral (Category 2)
 Serious eye damage (Category 1)
 Carcinogenicity (Category 1B)

Classification according to the directive 67/548/EEC
 May cause cancer. Toxic if swallowed. Risk of serious eye damage. R45; R25; R41

2.2. Elements of the label

Labelling according to (EC) Regulation no. 1272/2008 [CLP]



Hazard indications

H300 Fatal if swallowed.

H318 Causes serious eye damage.

H350 May cause cancer.

Precautionary statements

P201 Obtain special instructions before use.

P264 Wash hands carefully after use.

P280 Wear protective gloves/protective clothing/eye protection/face protection.

P301 + P310 IN CASE OF INGESTION: immediately contain a POISON CONTROL CENTRE or a doctor P305 + P351 + P338 IN CASE OF CONTACT WITH EYES: rinse thoroughly for several minutes. Remove contact lenses if possible to do so. Continue to rinse.

P308 + P313 IN CASE of exposure or possible exposure, consult a doctor.

2.3. Other hazards

N/A

3. COMPOSITION / INFORMATION ON INGREDIENTS

<u>Ingredient</u>	<u>Percent (%)Per Vial</u>	<u>CAS No.</u>
Cisplatin	0.05	15663-27-1
Sodium Chloride	**	7647-14-5
Mannitol	**	69-65-8
Hydrochloric Acid	**	7647-01-0

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Water for Injection

**

7732-18-5

**Additional Information: Ingredients indicated as hazardous have been assessed under standards for workplace safety. In accordance with 29 CFR 1910.1200, the exact percentage composition of this mixture has been withheld as a trade secret.

4. FIRST AID MEASURES

4.1 Description of the first aid measures

EYE EXPOSURE: Rinse thoroughly and abundantly with water for at least 15 minutes and contact a doctor.

SKIN EXPOSURE: Wash with soap and a lot of water. Immediately take the casualty to hospital. Consult a doctor.

INGESTION: Do not administer anything to an unconscious person. Rinse the mouth with water. Consult a doctor.

INHALATION: If inhaled, take the person into the fresh air. If not breathing, administer artificial respiration. Consult a doctor.

GENERAL NOTES Consult a doctor. Show this safety sheet to the doctor.

4.2. Main symptoms and effects, both acute and delayed

No information

4.3. Indication of any need to immediately consult a doctor and special treatments

No information

5. FIRE FIGHTING MEASURES

5.1. Extinguishing media

Suitable extinguishing media

Use water spray, alcohol-resistant foam, dry chemical products or carbon dioxide.

5.2. Special hazards deriving from the substance or the mixture

Hazardous combustion products: oxides of carbon, oxides of nitrogen (NOx), hydrochloric acid gas

5.3. Advice for fire-fighters

In case of fire, wear respiratory protection devices, if necessary, with an independent air supply.

6. ACCIDENTAL RELEASE MEASURE

6.1. Personal precautions, protective equipment and emergency procedures

Use respiratory protection. Avoid the formation of dust. Avoid breathing vapours/mist/gas. Provide adequate ventilation. Evacuate the personnel to safe areas. Do not inhale dust.

6.2. Environmental precautions

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Avoid leakage or spillage, if this can be achieved safely. Do not allow the product to enter drains.

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6. ACCIDENTAL RELEASE MEASURE (CONT)

6.3. Methods and materials for containment and cleaning up

Collect and dispose of without creating dust. Sweep up and shovel. Store in suitable containers and seal for disposal.

6.4. References to other sections

For disposal, refer to section 13.

7. HANDLING AND STORAGE

7.1. Precautions for safe handling

Avoid contact with eyes and skin. Avoid the formation of dust and the dispersal of the product. Arrange suitable ventilation in places where dust gathers. Normal fire prevention measures.

7.2. Conditions for safe storage, including any incompatibilities

Store in a well-ventilated place. Keep the container hermetically sealed in a dry and well-ventilated environment.

7.3 Specific end uses

see section 1.2

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

8.1 CONTROL PARAMETERS

Does not contain substance with a limit value for professional exposure.

8.2 EXPOSURE CONTROLS

SUITABLE TECHNICAL CONTROLS:

Avoid contact with skin, eyes and clothing. Wash hands before breaks and after handling the product.

RESPIRATORY PROTECTION:

Should the risk assessment involve the need for purified air respirators, use a filtering facemask with P3 (EN 143) type of filter as backup for the technical measures. If the respirator is the only means of protection, use a full-face ventilated system. Use respirators and components tested and approved by the competent regulatory bodies, such as NIOSH (USA) and CEN (EU).

EYE and FACE PROTECTION:

Visor and protective goggles. Use eye protection equipment tested and approved in accordance to the requirements of the appropriate technical standards like NIOSH (USA) or EN 166 (EU).

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8. EXPOSURE CONTROLS / PERSONAL PROTECTION (CONT)

SKIN PROTECTION:

Protection of the hands: Handle with gloves. The gloves must be checked before use. Use an appropriate technique for the removal of gloves (without touching the external surfaces of the glove) in order to avoid skin contact with this product. Dispose of contaminated gloves after use in accordance with the current regulations and good laboratory practice. Wash and dry hands. The selected protective gloves must satisfy the requirements of the EU directive 89/686/EEC and the EN 374 standards drawn from it. Other skin protection: Complete protective clothing resistant to chemical substances. The type of protective equipment must be selected on the basis of the concentration and quantity of hazardous substance in the workplace.

9. PHYSICAL AND CHEMICAL PROPERTIES

9.1 Information on the basic physical and chemical properties

PHYSICAL STATE: Solid lyophilized crystalline powder

- a) Appearance: White to Light Yellow Lyophilized Powder
- b) Odour: odourless
- c) Olfactory threshold: N/A
- d) pH: N/D
- e) Melting point/freezing point: - 270°C
- f) Initial boiling point and boiling range: N/A
- g) Flash point: N/A
- h) Evaporation velocity: N/D
- i) Flammability: N/D
- j) Upper/lower limits of flammability or explosiveness: N/D
- k) Vapour pressure: N/D
- l) Vapour density: N/D
- m) Relative density: 3,738 g/cm³
- n) Solubility: 2.53X10⁺³ mg/l at 25° C in water; insoluble in most solvents except dimethylformamide
- o) n-Octanol/water partition coefficient: log Kow = -2.19
- p) Autoignition temperature: N/D
- q) Decomposition temperature: 270°C
- r) Viscosity: N/D
- s) Explosive properties: N/D
- t) Oxidising properties: N/D

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10. STABILITY AND REACTIVITY

10.1 Reactivity	Not determined
10.2 Chemical Stability	Not determined
10.3 Possibility of Hazardous Reactions	Not determined
10.4 Conditions to be Avoided	Not determined
10.5 Incompatible Materials	Strong Oxidizing Agents
10.6 Hazardous Decomposition Products	Not Determined

11. TOXICOLOGICAL INFORMATION

a) Acute toxicity: DL50 Oral - rat – 25.8 mg/Kg
 Observations: Behavioral: alterations in motor activity (specific test) Diarrhea Blood: normocytic anaemia
 DL50 Parenteral – frog – 17 mg/kg
 DL50 Intraperitoneal – guinea pig – 9.7 mg/kg
 DL50 Intramuscular – mouse – 17.9 mg/kg
 DL50 Intraperitoneal – mouse – 6.6 mg/kg
 DL50 Intravenous – mouse – 11 mg/kg
 DL50 Oral - mouse – 32.7 mg/kg
 DL50 Parenteral – mouse – 22 mg/kg
 DL50 Intramuscular – rat – 9.2 mg/kg
 DL50 Subcutaneous – mouse – 13 mg/kg
 DL50 Intraperitoneal – rat – 6.4 mg/kg
 DL50 Intravenous – rat – 8 mg/kg
 DL50 Subcutaneous – mouse – 13 mg/kg
 LDLo Intravenous – dog – 2.5 mg/kg
 TDLo Intradermal – human – 0.00004 mg/kg
 TDLo Intravenous – human – 0.5 mg/kg Symptoms: acute renal failure, acute tubular necrosis
 TDLo Intravenous – human – 1.5 mg/kg Symptoms: in addition to those given above, a variation of the bone marrow, loss of hearing have been recorded
 TDLo Intravenous – human – 2.5 mg/kg Symptoms: in addition to those given above, for the 2 lower doses, hallucination, nausea and vomiting have been recorded

b) Skin corrosion/irritation: can cause severe skin irritation
 c) Serious eye damage/serious eye irritation: N/D
 d) Respiratory or skin sensitization: Repeated or prolonged exposure can cause allergic reaction in some sensitive subjects.
 e) Geminal cell mutagenicity: N/D
 f) Carcinogenicity: Carcinogenicity - mouse - intraperitoneal
 Tumorigenic: Neoplastic according to RTECS Skin and adnexa: other: tumors Tumorigenic effects:

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11. TOXICOLOGICAL INFORMATION (CONT)

- f) Carcinogenicity: Carcinogenicity - mouse - intraperitoneal
Tumorigenic: Neoplastic according to RTECS Skin and adnexa: other: tumors Tumorigenic effects: tumors of the uterus
Carcinogenicity - mouse - intraperitoneal
Tumorigenic: carcinogen according to RTECS Lungs, chest or breathing: tumors
Possible carcinogen for humans
IARC: 2A - Group 2A: Probably carcinogenic for humans (Cisplatin)
- g) Reproductive toxicity: N/D
- h) Specific target organ toxicity (STOT) – single exposure: N/D
- i) Specific target organ toxicity (STOT) – repeated exposure: N/D
- j) Hazard in the event of aspiration: N/D

Potential health consequences:

Inhalation

Can be harmful if inhaled. Can cause irritation to the airways

Ingestion

Can be fatal if swallowed.

Skin

Can be harmful if absorbed through the skin. Can cause irritation of the skin.

Eyes

Causes burning of the eyes.

Further information : RTECS: TP2450000

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12. ECOLOGICAL INFORMATION

12.1. Toxicity

Not Determined

12.2. Persistence and degradability

Not Determined

12.3 Bioaccumulative potential

Not Determined

12.4 Mobility in soil

Not Determined

12.5. Results of PBT and vPvB assessment

Not Determined

12.6. Other harmful effects

Not Determined

12.7 Supplementary indications

Not Determined

13. DISPOSAL CONSIDERATIONS

13.1. Waste treatment methods

Assign non-recyclable waste and surpluses to an authorised waste disposal company. For the disposal of this product, use a specialist waste disposal company. Solubilise or mix the product with a combustible solvent, then burn in an incinerator for chemical products equipped with an afterburner and scrubber. Contaminated containers Dispose of as an unused product.

14. TRANSPORT INFORMATION

14.1 UN Number

ADR/RID: 3288 IMDG: 3288 IATA: 3288

14.2 UN proper shipping name.

ADR/RID: TOXIC SOLID, ORGANIC N.A.S. (Cisplatin) IMDG: TOXIC SOLID, INORGANIC, N.O.S. (Cisplatin)
IATA: Toxic solid, inorganic, n.o.s. (Cisplatin)

14.3 Classes of hazard connected to transport

ADR/RID: 6.1 IATA: 6.1 IMDG: 6.1

14.4 Packaging unit

ADR/RID: II IATA: II

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14. TRANSPORT INFORMATION (CONT)

14.5 Environmental hazards

ADR/RID: no IMDG Marine pollutant: no IATA: no

14.6 Special precautions for users.

Not Determined

14.7 Transport in bulk according to attachment II of MARPOL 73/78 and the IBC code

Not Determined

15. REGULATORY INFORMATION

Below is selected regulatory information chosen primarily for possible WG Critical Care use. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your city / state / country.

US Regulations

- TSCA – No
- CERCLA-No
- SARA 302 – No
- SARA 313 – No
- OSHA Substance Specific – No

State Regulations:

- Massachusetts: Not Listed
- New York: Listed
- New Jersey: Not listed
- Pennsylvania: Listed
- California Prop 65: Listed

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16. OTHER INFORMATION

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

History:

Revision Date MM / DD / YYYY: 04/22/2019

06/13/2019: Updated section 1 / Product Name

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