



Cisplatin Injection

1. IDENTIFICATION OF THE SUBSTANCE/PREPARATION AND THE COMPANY/UNDERTAKING

Manufacturer:

GETWELL PHARMACEUTICALS

474, Udyog vihar, phase-V, Gurgaon -122016, Haryana, India.

Emergency Telephone No: 911244477981/ 11244477982

Contact E-Mail: info@worldofgetwell.com

Website:www.worldofgetwell.com

Material Name: Cisplatin Injection BP

Strength: 10mg/10ml and 50mg/50ml
Chemical Family: Mixture
Intended Use: Pharmaceutical product used as Antineoplastic

2. HAZARDS IDENTIFICATION

Appearance: Aqueous sterile solution

Statement of Hazard: May cause cancer.
May cause genetic defects.

Additional Hazard Information:

Short Term: May cause eye and skin irritation (based on components) May be fatal if swallowed
Long Term: Repeat-dose studies in animals have shown a potential to cause adverse effects on kidneys and blood and blood forming organs Animal studies have shown a potential to cause adverse effects on the fetus.

Known Clinical Effects: Effects on blood and blood-forming organs have also occurred.

EU Indication of danger: Mutagenic: Category 2
Carcinogenic: Category 2

EU Risk Phrases:

R45 - May cause cancer.
R46 - May cause heritable genetic damage.
Hazardous Substance. Non-Dangerous Goods.

Australian Hazard Classification (NOHSC):

Note: This document has been prepared in accordance with standards for workplace safety, which require the inclusion of all known hazards of the active substance or its intermediates regardless of the potential risk. The precautionary statements and warnings included may not apply in all cases. Your needs may vary depending upon the potential for exposure in your workplace.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Ingredient	CAS Number	EU EINECS/ELINCS List	EU Classification	%
Cisplatin	15663-27-1	239-733-8	Repr.Cat.2;R61 Mut.Cat.2;R46 Carc.Cat.2;R45 T;R25	0.1



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Hydrochloric Acid	7647-01-0	231-595-7	C;R35 T;R23	**
Sodium hydroxide	1310-73-2	215-185-5	C;R35	**

Additional Information:

* Proprietary
 ** to adjust pH
 Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

4. FIRST AID MEASURES

Eye Contact: Flush with water while holding eyelids open for at least 15 minutes. Seek medical attention immediately.

Skin Contact: Remove contaminated clothing. Flush area with large amounts of water. Use soap. Seek medical attention.

Ingestion: Never give anything by mouth to an unconscious person. Wash out mouth with water. Do not induce vomiting unless directed by medical personnel. Seek medical attention immediately.

Inhalation: Remove to fresh air and keep patient at rest. Seek medical attention immediately.

Symptoms and Effects of Exposure: For information on potential signs and symptoms of exposure, See Section 2 - Hazards Identification and/or Section 11 - Toxicological Information.

5. FIRE FIGHTING MEASURES

Extinguishing Media: Use carbon dioxide, dry chemical, or water spray.

Hazardous Combustion Products: Formation of toxic gases is possible during heating or fire.

Fire Fighting Procedures: During all fire fighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

Fire / Explosion Hazards: Fine particles (such as dust and mists) may fuel fires/explosions.

6. ACCIDENTAL RELEASE MEASURES

Health and Safety Precautions: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

Measures for Cleaning / Collecting: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

Measures for Environmental Protections: Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

Additional Consideration for Large Spills: Non-essential personnel should be evacuated from affected area. Report emergency situations immediately. Clean up operations should only be undertaken by trained personnel.

7. HANDLING AND STORAGE



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General Handling: Avoid breathing vapor or mist. Avoid contact with eyes, skin and clothing. When handling, use appropriate personal protective equipment (see Section 8). Wash thoroughly after handling. Releases to the environment should be avoided. Review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure or environmental releases. Potential points of process emissions of this material to the atmosphere should be controlled with dust collectors, HEPA filtration systems or other equivalent controls.

Storage Conditions: Store as directed by product packaging.

8. EXPOSURE CONTROLS / PERSONAL PROTECTION

Refer to available public information for specific member state Occupational Exposure Limits.

Cisplatin

OEL TWA-8 Hr:	2µg/m ³
ACGIH Threshold Limit Value (TWA)	0.002 mg/m ³ TWA
Australia TWA	0.002 mg/m ³
Austria OEL - MAKs	Listed
Belgium OEL - TWA	Listed
Czech Republic OEL - TWA	Listed
Denmark OEL - TWA	Listed
Finland OEL - TWA	Listed
Ireland OEL - TWAs	Listed
Netherlands OEL - TWA	Listed
OSHA - Final PELs - TWAs:	0.002 mg/m ³
Portugal OEL - TWA	Listed
Romania OEL - TWA	Listed
Slovenia OEL - TWA	Listed

Environmental Exposure Controls: Refer to specific Member State legislation for requirements under Community environmental legislation.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE).

Hands: Impervious gloves are recommended if skin contact with drug product is possible and for bulk processing operations.

Eyes: Wear safety glasses or goggles if eye contact is possible.

Skin: Impervious protective clothing is recommended if skin contact with drug product is possible and for bulk processing operations.

Respiratory protection: If the applicable Occupational Exposure Limit (OEL) is exceeded, wear an appropriate respirator with a protection factor sufficient to control exposures to below the OEL.

9. PHYSICAL AND CHEMICAL PROPERTIES

Physical State:	Sterile solution	Color:	No data available.
Molecular Formula:	Mixture	Molecular Weight:	Mixture

10. STABILITY AND REACTIVITY

Chemical Stability: Stable under normal conditions of use.

Conditions to Avoid: Fine particles (such as dust and mists) may fuel fires/explosions.

Incompatible Materials: As a precautionary measure, keep away from strong oxidizers

11. TOXICOLOGICAL INFORMATION

General Information: The information included in this section describes the potential hazards of the individual ingredients.

Acute Toxicity: (Species, Route, End Point, Dose)

Cisplatin

Rat Oral LD 50 25.8 mg/kg
Rat Para-periosteal LD 50 8.0 mg/kg
Mouse Oral LD 50 32.7 mg/kg
Mouse Intravenous LD 50 11 mg/kg

Sodium hydroxide

Mouse IP LD50 40 mg/kg

Sodium chloride

Rat Oral LD50 3000 mg/kg
Mouse Oral LD50 4000 mg/kg

Mannitol

Rat Oral LD 50 13500 mg/kg
Mouse Oral LD 50 22 g/kg

12. ECOLOGICAL INFORMATION

Environmental Overview: Environmental properties have not been thoroughly investigated. Releases to the environment should be avoided.

13. DISPOSAL CONSIDERATIONS

Waste Treatment Methods:

Dispose of waste in accordance with all applicable laws and regulations. Member State specific and Community specific provisions must be considered. Considering the relevant known environmental and human health hazards of the material, review and implement appropriate technical and procedural waste water and waste disposal measures to prevent occupational exposure and environmental release. It is recommended that waste minimization be practiced. The best available technology should be utilized to prevent environmental releases. This may include destructive techniques for waste and wastewater.

14. TRANSPORT INFORMATION

DOT Not Regulated
Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

EU Symbol: T
EU Indication of danger: Mutagenic: Category 2
Carcinogenic: Category 2

EU Risk Phrases: R45 - May cause cancer.



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R46 - May cause heritable genetic damage.

EU Safety Phrases:

S22 - Do not breathe dust.
S53 - Avoid exposure - obtain special instructions before use.
S36/37 - Wear suitable protective clothing and gloves.

OSHA Label:

DANGER
May cause cancer.
May cause genetic defects.

Canada - WHMIS: Classifications

WHMIS hazard class:

Class D, Division 2, Subdivision A

Cisplatin

California Proposition 65

Inventory - United States TSCA - Sect. 8(b)

Australia (AICS):

Standard for the Uniform Scheduling

for Drugs and Poisons:

EU EINECS/ELINCS List

Listed: Cancer

Listed

Listed

Schedule 4

239-733-8

16. OTHER INFORMATION

Text of R phrases mentioned in Section 3

R23 - Toxic by inhalation.

R25 - Toxic if swallowed.

R35 - Causes severe burns.

R45 - May cause cancer.

R46 - May cause heritable genetic damage.

R61 - May cause harm to the unborn child.

Data Sources: Publicly available toxicity information. Safety data sheets for individual ingredients.

Prepared by:

Getwell Pharmaceuticals

Getwell Pharmaceuticals believes that the information contained in this Material Safety Data Sheet is accurate, and while it is provided in good faith, it is without warranty of any kind, expressed or implied. If data for a hazard are not included in this document there is no known information at this time.

End of Safety Data Sheet