

MATERIAL SAFETY DATA SHEET

Version No: MSDS/Cisp-AUS/DP-004

Effective Date: 11th November 2024

CISPLATIN INJECTION
10 MG/10 ML, 25 MG/25 ML, 50 MG/50 ML AND 100 MG/100 ML

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: Cisplatin Accord Injection
10 mg/10 mL, 25 mg/25 mL, 50 mg/50 mL, and 100 mg/100 mL

Sponsor	Manufacturer-1	Manufacturer-2
Accord Healthcare Pty Ltd Level 24, 570 Bourke Street, Melbourne, VIC, 3000, Australia Telephone: 1800 222 673 (hours 8:30am – 4:30pm)	Intas Pharmaceuticals Ltd. Plot No. 457, 458 Village-Matoda, Bavla Road, Ta. Sanand, Dist. Ahmedabad-382 210, Gujarat, India	Intas Pharmaceuticals Ltd. Plot No. 5, 6 and 7, Pharmez, Near Matoda Village, Ahmedabad-382 213, Gujarat, India

SECTION 2 – HAZARD(S) IDENTIFICATION

Classification of the Substance or Mixture:

GHS – Classification:

Germ cell mutagenicity : Category 1B
Carcinogenicity : Category 1B
Reproductive toxicity : Category 1B

Label Elements:



Signal Word: Danger

Hazard Statements:

H340 - May cause genetic defects
H350 - May cause cancer
H360D - May damage the unborn child
H362 - May cause harm to breast-fed children

Precautionary Statements:

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- P201 - Obtain special instructions before use.
- P202 - Do not handle until all safety precautions have been read and understood.
- P281 - Use personal protective equipment as required.
- P308 + P313 - If exposed or concerned: Get medical advice/attention.
- P405 - Store locked up.
- P501 - Dispose of contents/container in accordance with local, state, federal and provincial regulations.

Other Hazards: This product is intended for therapeutic use only when prescribed by a physician. Potential adverse reactions from prescribed doses and overdoses are described in the package insert.

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

SECTION 3 – COMPOSITION / INFORMATION ON INGREDIENTS

Active: Cisplatin.

Inactive: Sodium chloride, Sodium hydroxide, Hydrochloric acid, Water for Injection.

Ingredient	CAS Number	EU EINECS/ELINCS List	GHS Classification	%
Cisplatin	15663-27-1	239-733-8	Acute Tox.2 (H300) Carc.1B (H350) Repr.1B (H360D) Muta.1B (H340)	0.1%
Sodium chloride	7647-14-5	231-598-3	Not Listed	0.9%
Sodium hydroxide	1310-73-2	215-185-5	Skin Corr.1A (H314)	
Hydrochloric acid	7647-01-0	231-595-7	Press. Gas Skin Corr.1A (H314) Acute Tox.3 (H331)	
Water for Injection	7732-18-5	231-791-2	Not Listed	90%

Additional Information:

Ingredient(s) indicated as hazardous have been assessed under standards for workplace safety.

For the full text of the CLP/GHS abbreviations mentioned in this Section, see Section 16

SECTION 4 - FIRST AID MEASURES

Description of Necessary First Aid Measures:

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

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Skin Contact: Remove contaminated clothing. Wash skin with plenty of soap and water for 15 to 20 minutes. 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.

Medical Conditions Aggravated by Exposure: None known.

Injection: In cases of accidental injection, wash and disinfect area, seek medical attention.

Medical Attention and Special Treatment: See patient package insert in shipping carton for complete information.

SECTION 5 - FIRE FIGHTING MEASURES

Suitable Extinguishing Media: Use alcohol resistant foam, Water fog, Dry chemical powder, Carbon dioxide (CO₂) or spray when fighting fires involving this material. Use extinguishing measures that are appropriate to local circumstances and the surrounding environment.

Special Hazards Arising from the Substance or Mixture: Thermal decomposition products may include smoke and toxic fumes. Oxides of carbon, oxides of nitrogen and other organic substances may be formed. Other undetermined low molecular weight hydrocarbon compounds may be released in small quantities depending upon specific conditions of combustion.

Special Protective Equipment and Precautions for Fire-Fighters: During all firefighting activities, wear appropriate protective equipment, including self-contained breathing apparatus.

SECTION 6 - ACCIDENTAL RELEASE MEASURES

Personal Precautions, Protective Equipment and Emergency Procedures: Personnel involved in clean-up should wear appropriate personal protective equipment (see Section 8). Minimize exposure.

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

Methods and Material for Containment and Cleaning Up: Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly.

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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.

Release to Air: If aerosolized, reduce exposures by ventilating area. Clean up immediately.

Release to Water: Refer to local and regional water authority requirements.

SECTION 7 - HANDLING AND STORAGE

Precautions for Safe Handling: Eliminate possible ignition sources (e.g., heat, sparks, flame, impact, friction, electricity), and follow appropriate grounding and bonding procedures. Avoid contact with eyes, skin and clothing. Avoid breathing vapor or mist. Use with adequate ventilation.

Caution should be exercised in handling the aqueous solution. Procedures for proper handling and disposal of anticancer drugs should be utilized. Several guidelines on this subject have been published. To minimize the risk of dermal exposure, always wear impervious gloves when handling vials and IV sets containing cisplatin.

Skin reactions associated with accidental exposure to cisplatin may occur. The use of gloves is recommended. If cisplatin contacts the skin or mucosa, immediately and thoroughly wash the skin with soap and water and flush the mucosa with water.

Conditions for Safe Storage, Including any Incompatibilities: Store as directed by product packaging.

Specific end use(s): Pharmaceutical product used as Antineoplastic.

SECTION 8 - EXPOSURE CONTROLS / PERSONAL PROTECTION

Control Parameters – Exposure Standards, Biological Monitoring:

Cisplatin:

OEL TWA-8 Hr	: 2µg/m ³
ACGIH Threshold Limit Value (TWA)	: 0.002 mg/m ³
Australia TWA	: 0.002 mg/m ³
OSHA - Final PELs - TWAs	: 0.002 mg/m ³
	(vacated) TWA: 0.002 mg/m ³ Pt

Hydrochloric acid:

ACGIH Ceiling Threshold Limit	: 2 ppm
Australia PEAK	: 5 ppm

Sodium hydroxide:

ACGIH Ceiling Threshold Limit	: 2 mg/m ³
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Australia PEAK : 2 mg/m³

Appropriate Engineering Controls: Engineering controls should be used as the primary means to control exposures. General room ventilation is adequate unless the process generates dust, mist or fumes. Keep airborne contamination levels below the exposure limits listed above in this section.

Personal Protective Equipment: Refer to applicable national standards and regulations in the selection and use of personal protective equipment (PPE). Contact your safety and health professional or safety equipment supplier for assistance in selecting the correct protective clothing/equipment based on an assessment of the workplace conditions, other chemicals used or present in the workplace and specific operational processes.

Hands: Impervious disposable gloves (e.g. Nitrile, etc.) (double recommended) if skin contact with drug product is possible and for bulk processing operations. (Protective gloves must meet the standards in accordance with EN374, ASTM F1001 or international equivalent.)

Eyes: Wear safety glasses or goggles if eye contact is possible. (Eye protection must meet the standards in accordance with EN166, ANSI Z87.1 or international equivalent.)

Respiratory protection: Under normal conditions of use, 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 (e.g. particulate respirator with a half mask, P3 filter). (Respirators must meet the standards in accordance with EN140, EN143, ASTM F2704-10 or international equivalent.)

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: Solution
Colour	: Clear, colourless
Odour	: No data available
Odour Threshold	: No data available
Solubility	: Soluble in water or saline at 1 mg per mL and in dimethylformamide at 24 mg per mL
pH	: 3.8 – 5.9
Melting (°C)	: 207°C
Boiling Point (°C)	: 100°C
Partition Coefficient (<i>n-octanol/water</i>)	: No data available
Decomposition Temperature (°C)	: No data available
Evaporation Rate (Gram/s)	: No data available
Vapour Pressure (kPa)	: No data available
Vapour Density (g/ml)	: No data available
Relative Density	: No data available
Viscosity	: No data available
Auto-ignition Temperature (°C)	: No data available
Flammability	: No data available
Flash Point (°C)	: No data available

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Upper Flammability or Explosive Limits (% by Vol.) : No data available

Lower Flammability or Explosive Limits (% by Vol.) : No data available

SECTION 10 - STABILITY AND REACTIVITY

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

Chemical Stability: Stable under normal conditions of use.

Conditions to Avoid: Protect from light, heat, and freezing.

Incompatible Materials and Possible Hazardous Reactions: Avoid contact with incompatible oxidizing agents of aluminum, sodium bicarbonate, sodium bisulfate, and sodium metabisulfate.

Hazardous Decomposition Products: No data available.

SECTION 11 – TOXICOLOGICAL INFORMATION

The information included in this section describes the potential hazards of the active ingredient.

Information on Toxicological Effects:

Likely Routes of Exposure: Inhalation, eye/skin contact or ingestion.

Acute Toxicity:

Cisplatin:

Species	Route	End Point	Dose
Rat	Subcutaneous	LD50	8100 mcg/kg
Mouse	Subcutaneous	LD50	16,900 mcg/kg
Mouse	Subcutaneous	LD50	13 mg/kg
Rat	Intravenous	LD50	8 mg/kg
Mouse	Intravenous	LD50	11 mg/kg
Rat	Intramuscular	LD50	9200 mcg/kg
Mouse	Intramuscular	LD50	7900 mcg/kg
Mouse	Oral	LD50	32.7 mg/kg

Sodium hydroxide:

Species	Route	End Point	Dose
Mouse	Intraperitoneal	LD50	40 mg/kg

Sodium chloride:

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Species	Route	End Point	Dose
Rat	Oral	LD50	3000 mg/kg
Mouse	Oral	LD50	4000 mg/kg

Hydrochloric acid:

Species	Route	End Point	Dose
Rat	Oral	LD50	13,500 mg/kg
Mouse	Oral	LD50	22 g/kg

Symptoms related to the physical, chemical and toxicological characteristics: No data available.

Delayed and immediate effects and chronic effects from short and long term exposure: No data available.

Carcinogen Status:

Cisplatin:

NTP : Reasonably Anticipated To Be A Carcinogen
IARC : Group 2A - Probably Carcinogenic to Humans
OSHA : Present

Hydrochloric Acid:

IARC : Group 3

SECTION 12 – ECOLOGICAL INFORMATION

Environmental Overview: The environmental characteristics of this material have not been fully evaluated. Releases to the environment should be avoided.

Ecotoxicity: No data available.

Persistence and Degradability: No data available.

Bio-accumulative Potential: No data available.

Mobility in Soil: No data available.

Other Adverse Effects: No data available.

SECTION 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

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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.

SECTION 14 - TRANSPORTATION INFORMATION

The following refers to all modes of transportation unless specified below.

DOT	: Not regulated as a dangerous good
IATA	: Not regulated as a dangerous good
IMDG	: Not regulated as a dangerous good
UN Number	: Not Available
UN Proper Shipping Name	: Not Available
Transport Hazard Class(es)	: Not Available
Packing Group	: Not Available
Environmental Hazards	: Not Available
Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	: Not Available
Special Precautions	: Not Available

SECTION 15 - REGULATORY INFORMATION

Safety, Health and Environmental Regulations/Legislation Specific for the Substance or Mixture

Cisplatin:

CERCLA/SARA 313 Emission reporting	: Not Listed
California Proposition 65	: Listed - Cancer
EU EINECS/ELINCS List	: 239-733-8
Inventory - United States TSCA - Sect. 8(b)	: Listed
OSHA Label	: WARNING Possible carcinogen and mutagen

SECTION 16 - OTHER INFORMATION

Abbreviations:

ACGIH	: American Conference of Governmental Industrial Hygienists
AICS	: Australian Inventory of Chemical Substances
AIHA	: American Industrial Hygiene Association
ANSI	: American National Standards Institute
CAS	: Number Chemical Abstract Service Registry Number
CERCLA	: Comprehensive Environmental Response Compensation and Liability Act
CHAN	: Chemical Hazard Alert Notice
CHEMTREC	: Chemical Transportation Emergency Center

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DOT	: Department of Transportation
DSL	: Domestic Substances List
ECHA	: European Chemicals Agency
EINECS	: European Inventory of Existing Commercial Chemical Substances
ELINCS	: European List of Notified Chemical Substances
EPA	: Environmental Protection Agency
GHS	: Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	: High Efficiency Particulate Air (Filter)
HMIS	: Hazardous Materials Identification System
IARC	: International Agency for Research on Cancer
ICAO/IATA	: International Civil Aviation Organization/International Air Transport
IMO	: International Maritime Organization
KOW	: Octanol/Water Partition Coefficient
LEL	: Lower Explosive Limit
MSDS	: Material Safety Data Sheet
MSHA	: Mine Safety and Health Administration
NA	: Not Applicable, except in Section 14 where NA = North America
NE	: Not Established
NADA	: New Animal Drug Application
NAIF	: No Applicable Information Found
NCI	: National Cancer Institute
NDSL	: Non-Domestic Substances List
NFPA	: National Fire Protection Association
NIOSH	: National Institute for Occupational Safety and Health
NPDES	: National Pollutant Discharge Elimination System
NOS	: Not Otherwise Specified
NTP	: National Toxicology Program
OSHA	: Occupational Safety and Health Administration
OEL	: Occupational Exposure Limit
PEL	: Permissible Exposure Limit (OSHA)
RCRA	: Resource Conservation and Recovery Act
RQ	: Reportable Quantity
RTECS	: Registry of Toxic Effects of Chemical Substances
SARA	: Superfund Amendments and Reauthorization Act
SDS	: Safety Data Sheet
STEL	: Short Term Exposure Limit
TLV	: Threshold Limit Value (ACGIH)
TPQ	: Threshold Planning Quantity
TSCA	: Toxic Substances Control Act
TWA	: Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	: Upper Explosive Limit
UN	: United Nations
USP	: United States Pharmacopeia
WEEL	: Workplace Environmental Exposure Level (AIHA)
WHMIS	: Workplace Hazardous Materials Information System

Data Sources: Information from published literature.

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