

MATERIAL SAFETY DATA SHEET

Version No: MSDS/Cisp-AUS/DP-003

Effective date: 05th October 2019

CISPLATIN INJECTION 1 mg/mL, 10 mL, 25 mL, 50 mL and 100 mL

SECTION 1 – PRODUCT AND COMPANY IDENTIFICATION

Product Name: Cisplatin Injection 1 mg/mL, 10 mL, 25 mL, 50 mL and 100 mL

Sponsor	Manufacturer-1	Manufacturer-2
Accord Healthcare Pty Ltd Level 24, 570 Bourke Street Melbourne, VIC, 3000, Australia	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 – COMPOSITION, INFORMATION ON INGREDIENTS

Active: cisplatin

Inactive: sodium chloride, sodium hydroxide, hydrochloric acid, water for Injections

Chemical Name	Common Name / Synonym	% Composition or other measure	CAS No.	Impurities / Stabilizing Additives
cisdiamminedichloridoplatinum(II)	Cisplatin	0.1%	15663-27-1	N/A
Sodium chloride, hydrochloric acid and/or sodium hydroxide	Sodium chloride, hydrochloric acid, sodium hydroxide	0.9%	7647-14-5 7647-01-0 1310-73-2	N/A
Water for Injection	Water	90%	7732-18-5	N/A

SECTION 3 – HARZARDS IDENTIFICATION

Classification:

GHS Classification:

Acute Oral Toxicity	: Category 2
Serious Eye Damage	: Category 1
Skin corrosion	: Category 1
Respiratory sensitization	: Category 1
Carcinogenicity	: Category 1B
Reproductive toxicity	: Category 2
Skin Sensitization	: Category 10
Reproductive toxicity	: Effects on or via lactation

Signal Word, Hazard statement(s), Symbol(s), and/or Precautionary statement(s):

Signal Word: Danger

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Hazard Statement:

- Fatal if swallowed
- Causes serious eye damage.
- Causes severe skin burns and eye damage
- May cause allergy or asthma symptoms or breathing difficulties if inhaled.
- May cause cancer.
- Suspected of damaging fertility or the unborn child.
- May cause an allergic skin reaction.
- May cause harm to breast-fed children.

Symbols:



GHS Precautionary Statements:

- Obtain special instructions before use.
- Do not handle until all safety precautions have been read and understood.
- Do not breathe dust/fume/gas/mist/vapors/spray.
- Avoid breathing dust/fume/gas/mist/vapors/spray.
- Avoid contact during pregnancy and while nursing.
- Wash hands thoroughly after handling.
- Do not eat, drink or smoke when using this product.
- Contaminated work clothing should not be allowed out of the workplace.
- Wear protective gloves/protective clothing/eye protection/face protection.
- In case of inadequate ventilation wear respiratory protection.
- If swallowed: Immediately call a Poison Center or doctor/physician.
- If swallowed: Rinse mouth. Do not induce vomiting.
- If on skin: wash with plenty of water.
- If on Skin or hair: remove take/off immediately all contaminated clothing. Rinse skin with water/shower.
- If inhaled: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
- If in eyes: rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.

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- If exposed or concerned: Get medical advice/attention. Immediately call a poison center or doctor/physician. Rinse mouth.
- If skin irritation or rash occurs: get medical advice/attention.
- If experiencing respiratory symptoms: call a poison center or doctor/physician.
- Take off contaminated clothing and wash it before reuse.
- Wash contaminated clothing before reuse.
- Store locked up.
- Dispose of contents/container in accordance with local, state, federal and provincial regulations.

Emergency Overview: 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.

Unknown Acute Toxicity N/A

SECTION 4 – EMERGENCY AND FIRST AID MEASURES

Eye Exposure: Immediately flush eyes with plenty of water for at least 15 to 20 minutes. Ensure adequate flushing of the eyes by separating the eyelids with fingers. Get immediate medical attention.

Skin Exposure: Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes. Get medical attention if irritation develops or persists.

Ingestion: If conscious, flush mouth out with water immediately. Call a physician or poison control center immediately. Do not induce vomiting unless directed to do so by medical personnel. Never give anything by mouth to an unconscious person.

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

Inhalation: Remove victim to fresh air and keep at rest in a position comfortable for breathing.

Notes to Physician: See patient package insert in shipping carton for complete information.

SECTION 5 – FIRE FIGHTING MEASURES

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.

Hazardous Combustion Products: 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 / Precautions: As in any fire, wear self-contained breathing apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear.

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SECTION 6 – ACCIDENTAL RELEASE MEASURES

Spill: Personnel involved in clean-up should wear appropriate personal protective equipment. Minimize exposure. Contain the source of spill if it is safe to do so. Collect spill with absorbent material. Clean spill area thoroughly. Place waste in an appropriately labeled, sealed container for disposal. Care should be taken to avoid environmental release.

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

General 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.

Storage Conditions: Store at 20° to 25°C (68° to 77°F). [See USP Controlled Room Temperature]. Do not refrigerate. Protect unopened container from light. The cisplatin remaining in the amber vial following initial entry is stable for 28 days protected from light or for 7 days under fluorescent room light.

SECTION 8 – EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Limits:

Compound	Issuer	Type	Exposure Limit
Cisplatin	OSHA ACGIH	PEL	0.002mg/m ³ TWA
		TLV	0.002mg/m ³ TWA
			1 mg/m ³ TWA
Hydrochloric Acid	ACGIH	CTL	2 ppm Ceiling
Sodium Hydroxide	OSHA ACGIH	PEL	2 mg/m ³ TWA
		CTL	2 mg/m ³ Ceiling
			1 mg/m ³ TWA

Engineering Controls: Engineering controls should be used as the primary means to control exposures. Local exhaust ventilation is required unless used in a closed system.

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Individual Protection Measures:

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.

Eye Protection: The use of chemical safety goggles (as a minimum) is recommended.

Skin Protection: Rubber gloves and protective clothing with long sleeves should be used to avoid skin contact. Wash hands and arms thoroughly after handling this product.

SECTION 9 – PHYSICAL AND CHEMICAL PROPERTIES

Appearance	: Clear, colorless, sterile aqueous solution
Odor	: Not available
Odor Threshold	: Not available
pH	: 3.8 to 5.9
Melting Point	: 207° C
Initial Boiling Point	: 100° C
Flash Point	: Not available
Evaporation Rate	: Not available
Flammability	: Not available
Upper Lower Flammability or Explosion Limits	: Not available
Vapor Pressure	: Not available
Vapor Density	: Not available
Relative Density	: Not available
Solubility(ies)	: Soluble in water or saline at 1 mg per mL and in dimethylformamide at 24 mg per mL
Partition Coefficient: n-octanol/water	: Not available
Auto-ignition Temperature	: Not available
Decomposition Temperature	: Not available
Viscosity	: Not available

SECTION 10 – STABILITY AND REACTIVITY

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

Chemical Stability Material is stable under normal conditions

Possibility of Hazardous Reactions Not reported

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

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

Hazardous Decomposition Products Not available.

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SECTION 11 – TOXICOLOGY INFORMATION

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

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.

Acute Toxicity: Based on available data, the classification criteria are not met.

Component	Type	Route	Species	Dosage
Cisplatin	LD50	Subcutaneous	Rat	8100 mcg/kg
	LD50	Subcutaneous	Mouse	16,900 mcg/kg
	LD50	Subcutaneous	Mouse	13 mg/kg
	LD50	Intravenous	Rat	8 mg/kg
	LD50	Intravenous	Mouse	11 mg/kg
	LD50	Intramuscular	Rat	9200 mcg/kg
	LD50	Intramuscular	Mouse	7900 mcg/kg
	LD50	Oral	Mouse	32.7 mg/kg
Sodium Hydroxide	LD50	Intraperitoneal	Mouse	40 mg/kg
Sodium Chloride	LD50	Oral	Rat	3000 mg/kg
	LD50	Oral	Mouse	4000 mg/kg
Hydrochloric Acid	LD50	Oral	Rat	13,500 mg/kg
	LD50	Oral	Mouse	22 g/kg

Hazardous Chemical Listings

Cisplatin:

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

Hydrochloric Acid:

IARC : Group 3

SECTION 12 – ENVIRONMENTAL IMPACT INFORMATION

Ecotoxicity: No data available

Persistence and degradability: No data available

Bioaccumulative potential: No data available

Mobility in soil: No data available

Other Adverse Effects: No data available

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SECTION 13 – DISPOSAL INFORMATION

Waste Disposal: Dispose of any cleanup materials and waste residue according to all applicable laws and regulations.

SECTION 14 – TRANSPORTATION INFORMATION

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

This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

TSCA : Listed
CERCLA : Not on this list
OSHA Label : WARNING Possible carcinogen and mutagen
EINECS Number : 239-733-8
California Prop 65 : Listed – Cancer

SECTION 16 – OTHER DATA

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
DOT	:	Department of Transportation
DSL	:	Domestic Substances List

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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

Sources of data: Information from published literature.

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