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Section 1 - Identification

- (a) **Product Identifier:** Cisplatin Injection
- (b) **Product Code:** 70860-206
- Common/Trade Name:** Platinol
- Chemical Name:** cis-diamminedichloridoplatinum(II)
- Chemical Family:** Antineoplastic
- (c) **Product Use:** Pharmaceutical, Injectable
- Product Type:** Regulated Prescription Drug
- Container Information:** Vial
- (d) **Distributor:** Athenex Pharmaceutical Division, 10 N. Martingale Road, Suite 230, Schaumburg, IL 60173, 847-886-9515
- (e) **Emergency Telephone:** 855-273-0154

Section 2 - Hazards Identification

- (a) **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

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

Signal Word: Danger

Hazard Statement:

- Fatal if swallowed
- Causes serious eye damage.
- Causes sever skin burns and eye damage
- May cause allergy or asthma symproms 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.

Don 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.

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If in eyes: rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
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.

(d) Unknown Acute Toxicity N/A

Section 3 – Composition / Information on Ingredients

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
cis-diamminedichloridoplatinum(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

* Sodium chloride, sodium hydroxide and/or hydrochloric acid may be added for pH adjustment.


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Section 4 – 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. **To report SUSPECTED ADVERSE REACTIONS, contact Athenex Pharmaceutical Division, LLC. at 1-855-273-0154 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.**

Section 5 – Fire-fighting Measures

- (a) **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.
- (b) **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.
- (c) **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

(a) Exposure Limits

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

Compound	Issuer	Type	Exposure Limit
Sodium Hydroxide	OSHA ACGIH	PEL CTL	2 mg/m ³ TWA 2 mg/m ³ Ceiling 1 mg/m ³ TWA

(b) 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.

(c) 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

(a)	Appearance	Clear, colorless, sterile aqueous solution
(b)	Odor	Not available
(c)	Odor Threshold	Not available
(d)	pH	3.8 to 5.9
(e)	Melting Point:	207° C
(f)	Initial Boiling Point:	100° C

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(g)	Flash Point	Not available
(h)	Evaporation Rate:	Not available
(i)	Flammability	Not available
(j)	Upper Lower Flammability or Explosion Limits	Not available
(k)	Vapor Pressure:	Not available
(l)	Vapor Density:	Not available
(m)	Relative Density	Not available
(n)	Solubility(ies)	Soluble in water or saline at 1 mg per mL and in dimethylformamide at 24 mg per mL
(o)	Partition Coefficient: n-octanol/water	Not available
(p)	Auto-ignition Temperature	Not available
(q)	Decomposition Temperature	Not available
(r)	Viscosity	Not available

Section 10 - Stability and Reactivity

(a)	Reactivity	The product is stable and non-reactive under normal conditions of use, storage and transport.
(b)	Chemical Stability	Material is stable under normal conditions
(c)	Possibility of Hazardous Reactions	Not reported
(d)	Conditions to Avoid	Protect from light, heat, and freezing.
(e)	Incompatible Materials	Avoid contact with incompatible oxidizing agents of aluminum, sodium bicarbonate, sodium bisulfate, and sodium metabisulfate.
(f)	Hazardous Decomposition Products	Not available.

Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Inhalation, eye/skin contact or ingestion.
(b)	Symptoms related to the physical, chemical and toxicological characteristics	No data available.
(c)	Delayed and immediate effects and chronic effects from short and long term exposure	No data available.

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(d) 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

(e) 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 - Ecological Information

(a) Ecotoxicity	No data available.
(b) Persistence and degradability	No data available.
(c) Bioaccumulative potential	No data available.
(d) Mobility in soil	No data available.
(e) Other Adverse Effects	No data available.

Section 13 - Disposal Considerations

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

Section 14 - Transport Information

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IATA: Not regulated as a dangerous good.

IMDG: Not regulated as a dangerous good.

(a)	UN Number	Not Available
(b)	UN Proper Shipping Name	Not Available
(c)	Transport Hazard Class(es)	Not Available
(d)	Packing Group	Not Available
(e)	Environmental Hazards	Not Available
(f)	Transport in bulk (according to Annex II of MARPOL 73/78 and the IBC Code)	Not Available
(g)	Special Precautions	Not Available

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Athenex Pharmaceutical Division usage. 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 Information

As of the date of effectiveness, 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.


For additional information contact:

Athenex Pharmaceutical Division
10 N. Martingale Road, Suite 230
Schaumburg, IL 60173
847-886-9515

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Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

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 (of
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
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

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UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System

Signature Manifest

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All dates and times are in Eastern Standard Time.

SDS Cisplatin Review/Approval

Change Request

Name/Signature	Title	Date	Meaning/Reason
Michael Scribner (MSCRIBNER)	Director of Quality	30 Jun 2017, 11:30:29 AM	Approved

Dept Approval

Name/Signature	Title	Date	Meaning/Reason
Tom Moutvic (TMOUTVIC)	VP of Regulatory Affairs		
John Andre (JANDRE)	Regulatory Affairs Consultant	05 Jul 2017, 01:03:47 PM	Approved

Final QA Approval/Set Effective Date

Name/Signature	Title	Date	Meaning/Reason
Sheila Moran (SMORAN)	VP of Quality Assurance	05 Jul 2017, 01:58:18 PM	Approved