

CISPLATIN INJECTION

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Product Identifier: Cisplatin
General Use: Antineoplastic

MANUFACTURER

American Pharmaceutical Partners, Inc.
1101 Perimeter Drive
Schaumburg, IL 60173-5837
(847) 969-2700

EMERGENCY TELEPHONE NUMBER:

(708) 450-7500

2. COMPOSITION/INFORMATION ON INGREDIENTS

Component: **Cisplatin**

CAS Registry #: 15663-27-1

OSHA PEL: 0.002 mg/m3 OSHA PEL: NE ppm
ACGIH TLV: 0.002 mg/m3 ACGIH TLV: NE ppm
STEL: NE mg/m3 STEL: NE ppm

Percent of Product: <1% Note: QS to volume

Component: **Sodium Chloride**

CAS Registry #: 7647-14-5

OSHA PEL: NE mg/m3 OSHA PEL: NE ppm
ACGIH TLV: NE mg/m3 ACGIH TLV: NE ppm
STEL: NE mg/m3 STEL: NE ppm

Percent of Product: <1% Note: QS to volume

3. HAZARD IDENTIFICATION

PRIMARY ROUTES OF EXPOSURE - Inhalation, Eye/Skin Absorption and Ingestion.

CHEMICAL LISTING AS CARCINOGEN: See also Section 11.

<u>COMPONENT</u>	<u>CAS No.</u>	<u>NTP</u>	<u>IARC</u>	<u>OSHA</u>
Cisplatin	15663-27-1	YES	2A	NO
Sodium Chloride	7647-14-5	NO	NO	NO

4. EMERGENCY AND FIRST AID PROCEDURES

INHALATION: Move person to fresh air immediately. Monitor for respiratory distress. If cough, difficulty in breathing or systemic signs or symptoms develop, seek medical attention. Give artificial respiration and cardiopulmonary resuscitation (CPR) if required.

INGESTION: Flush mouth out with water immediately. Seek medical attention.

SKIN CONTACT: Remove contaminated clothing immediately. Wash area very thoroughly with soap and water for at least 15 minutes. Seek medical attention if irritation or pain persists.

EYE CONTACT: Immediately flush with water for at least 15 minutes. Seek medical attention if irritation, lacrimation, light sensitivity, pain or swelling persists.

For Adverse Drug Reaction Information call (708) 547-2372.

5. FIRE FIGHTING MEASURES

Fire and Explosion Data:

Closed Cup Flash Pt.	NE
Open Cup Flash Pt.	NE
Fire Point	NE
Autoignition	NE
Lower Explosion Limit	NE
Upper Explosion Limit	NE

GENERAL HAZARD: When heated to decomposition it emits very toxic fumes of Cl- and NOx.

FIRE FIGHTING INSTRUCTION: Water spray, dry chemical, carbon dioxide or foam as appropriate.

FIRE FIGHTING EQUIPMENT: Wear self-contained breathing apparatus and protective clothing.

HAZARDOUS COMBUSTION PRODUCTS: Smoke, Cl- and NOx fumes.

6. ACCIDENTAL RELEASE MEASURES

CLEAN-UP: Wear recommended personal protective equipment. Use absorbent towels or booms to clean-up spill. Wipe surfaces clean and wash with soap and water at three times. Ventilate area.

7. HANDLING AND STORAGE

When handling pharmaceutical products, avoid all contact and inhalation of dust, fumes, mist, and/or vapors associated with the product.

Store between 15 - 25 °C (59 - 77 °F); protect from light; avoid refrigeration. Do not permit to freeze.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

ENGINEERING CONTROLS:

General room ventilation is usually satisfactory, use local exhaust ventilation when necessary. A biological safety cabinet is recommended for formulation, sampling and drawing up the product.

PERSONAL PROTECTION:

Respirators - NIOSH approved respirator.

Eyes - Safety glasses or goggles recommended

Gloves - A double layer of disposable latex gloves recommended.

Clothing - Disposable garments if direct skin contact is anticipated. Head cover, coverall, long sleeves, protect exposed skin.

See also section 14 (Other Information).

9. PHYSICAL AND CHEMICAL PROPERTIES

Appearance/Odor other characteristics: Clear, colorless solution.

Boiling Point:	NA	Vapor Density:	NA
Melting Point:	207° C	Percent Volatiles:	NA
Freezing Point:	NA	pH:	3.7 - 6.0
Vapor Pressure:	NA	Molecular Weight:	300.07
Note:		Solubility:	Soluble in water @1gm/100

10. STABILITY AND REACTIVITY

Stability - Stable. Store between 15 - 25C (59 - 77F).

Conditions/Materials to Avoid - Protect from light; avoid refrigeration: do not permit to freeze. Avoid oxidizing agents aluminum, sodium bicarbonate, sodium bisulfate and sodium metabisulfate.

Hazardous Polymerization - Will not occur.

11. TOXICOLOGY INFORMATION

SIGNS & SYMPTOMS OF OVEREXPOSURE MAY INCLUDE:

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. These may include: leukopenia: fever, chills, cough, hoarseness, lower back or side pain, painful/difficult urination; thrombocytopenia: Unusual bleeding or bruising, black tarry stools, blood in urine or stools, pin point red spots on skin; tiredness, weakness, joint pain, swelling of feet or legs; loss of balance, ringing in ears and trouble hearing. Occupational exposure has not been fully investigated.

LD50 (Oral Rat): 25.8 mg/Kg

MEDICAL CONDITIONS AGGRAVATED BY ACCIDENTAL EXPOSURE:

Sensitivity to the product, pregnancy and breast-feeding. Pre-existing skin and respiratory conditions.

IMMEDIATE EFFECTS: Eye, skin or respiratory tract irritation.

DELAYED EFFECTS: Possible hypersensitization and cancer.

12. TRANSPORT INFORMATION

UN/NA Number: NA
DOT Hazard Class: 6.1 POISON
Shipping Name: POISONOUS SOLIDS, N.O.S. (CISPLATIN)
Shipping Label: POISON

13. WASTE DISPOSAL

Waste Disposal - Waste product should be incinerated in accordance with federal, state and local regulations.

14. OTHER INFORMATION

KEY TO ABBREVIATIONS:

ACGIH - American Conference of Governmental Industrial Hygienists

HEPA - High-Efficiency Particulate Air

IARC - International Agency for Research on Cancer

NA - Not Applicable

NE - Not Established

NG - Not Given

NIOSH - National Institute for Occupational Safety and Health

NTP - National Toxicology Program

OSHA - Occupational Safety and Health Administration

PEL - Permissible Exposure Limit

PPM - Parts Per Million

QS - Quantity Sufficient

RCRA - Resource Conservation and Recovery Act

STEL - Short Term Exposure Limit

TLV - Threshold Limit Value

There is limited but increasing evidence that personnel involved in the preparation and administration of parenteral antineoplastics may be at some risk because of potential mutagenicity, teratogenicity and/or carcinogenicity of these agents although the actual risk is not known. USP advisory panels recommend cautious handling in both preparation and disposal of antineoplastic agents. Precautions that have been suggested include: Use of a biological containment cabinet during reconstitution and dilution of parenteral medications and wearing of disposable surgical gloves and masks; Use of proper technique to prevent contamination of medication, work area and operator during transfer between containers; Cautious and proper disposal of needles, syringes, vials, ampules and unused medication.
