# SAFETY DATA SHEET

## SECTION 1 : IDENTIFICATION

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|---|---|
| Product Name: | **Cisplatin Injection** |
| Manufacturer Name: | Fresenius Kabi USA, LLC |
| Address: | Three Corporate Drive<br>Lake Zurich, Illinois 60047 |
| General Phone Number: | (847) 550-2300 |
| Customer Service Phone Number: | (888) 386-1300 |
| Health Issues Information: | (800) 551-7176 |
| SDS Creation Date: | January 08, 2009 |
| SDS Revision Date: | June 10, 2015 |
| (M)SDS Format: | |

## SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:



Signal Word: DANGER.

GHS Class:

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

Hazard Statements:

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.

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/vapours/spray.
Avoid breathing dust/fume/gas/mist/vapours/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.
IF exposed or concerned: Get medical advice/attention.
Immediately call a POISON CENTER or doctor/physician.
Specific treatment (see ... on this label).
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.

Route of Exposure: Inhalation Ingestion Eye contact Skin Absorption. Injection.

Potential Health Effects:

Eye: Contact with eyes may cause irritation.

Signs/Symptoms: Adverse events from therapeutic doses include: nephrotoxicity, neuropathies, myelosuppression (leukopenia, thrombocytopenia, and anemia), fever, infection, nausea, vomiting, ototoxicity, tinnitis, hearing loss, deafness, and vestibular toxicity. Anaphylactic-like reactions of facial edema, bronchoconstriction, tachycardia, and hypotension have also been reported. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions: Individuals with pre-existing renal impairment, myelosuppression, hearing impairment, or previous history of allergic reaction to cisplatin or other platinumcontaining compounds.

## SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

| Chemical Name | CAS# | Ingredient Percent | EC Num. |
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| Cisplatin | 15663-27-1 | - % | |
| Sodium Chloride | 7647-14-5 | - % | |

## SECTION 4 : FIRST AID MEASURES

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| Eye Contact: | 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 Contact: | Immediately wash skin with plenty of soap and water for 15 to 20 minutes, while removing contaminated clothing and shoes.<br>Get medical attention if irritation develops or persists. |
| Inhalation: | If inhaled, remove to fresh air. If not breathing, give artificial respiration or give oxygen by trained personnel. Seek immediate medical attention. |
| 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. |
| Other First Aid: | For Adverse Event Information, please call (800) 551-7176. |

## SECTION 5 : FIRE FIGHTING MEASURES

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| Flash Point: | Not established. |
| Flash Point Method: | Not established. |
| Auto Ignition Temperature: | Not established. |
| Lower Flammable/Explosive Limit: | Not established. |
| Upper Flammable/Explosive Limit: | Not established. |
| Fire Fighting Instructions: | Evacuate area of unprotected personnel. Use cold water spray to cool fire exposed containers to minimize risk of rupture. Do not enter confined fire space without full protective gear. If possible, contain fire run-off water. |
| Extinguishing Media: | Use alcohol resistant foam, carbon dioxide, dry chemical, or water fog or spray when fighting fires involving this material.<br>Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. |
| Protective Equipment: | As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear. |
| Hazardous Combustion Byproducts: | 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. |

## SECTION 6 : ACCIDENTAL RELEASE MEASURES

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| Personnel Precautions: | Evacuate area and keep unnecessary and unprotected personnel from entering the spill area.<br>Avoid personal contact and breathing vapors or mists. Use proper personal protective equipment as listed in Section 8. |
| Environmental Precautions: | Avoid runoff into storm sewers, ditches, and waterways. |
| Methods for containment: | Contain spills with an inert absorbent material such as soil, sand or oil dry. |
| Methods for cleanup: | Absorb spill with inert material (e,g., dry sand or earth), then place in a chemical waste container. After removal, flush spill area with soap and water to remove trace residue. |

## SECTION 7 : HANDLING and STORAGE

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| Handling: | When handling pharmaceutical products, avoid all contact and inhalation of vapor, mists and/or fumes. Use with adequate ventilation. Use only in accordance with directions. |
| Storage: | Store at controlled room temperature 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature]. Do not refrigerate. Protect from light. |
| Work Practices: | Facilities storing or utilizing this material should be equipped with an eyewash facility and a safety shower. |
| Hygiene Practices: | Wash thoroughly after handling. Avoid contact with eyes and skin. Avoid inhaling vapor or mist. |

## SECTION 8: EXPOSURE CONTROLS, PERSONAL PROTECTION

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| Engineering Controls: | General ventilation is sufficient if this product is being used in a controlled medical setting (clinic, hospital, medical office) for its sole intended parenteral (injection) purpose. Otherwise, use appropriate engineering control such as process enclosures, local exhaust ventilation, or other engineering controls including use of a biosafety cabinet / fume hood to control airborne levels below recommended exposure limits. |
| Eye/Face Protection: | Chemical splash goggles. Wear a face shield also when splash hazard exist. |
| Skin Protection Description: | Protective laboratory coat, apron, or disposable garment recommended. |
| Hand Protection Description: | Wear appropriate protective gloves. Consult glove manufacturer's data for permeability data. Nitrile rubber or natural rubber gloves are recommended. |
| Respiratory Protection: | No personal respiratory protective equipment is normally required when this product is being used/administered by a licensed healthcare practitioner (i.e. an end-user such as a clinician / doctor / nurse) for its sole intended parenteral (injection) purpose in a controlled medical setting. The need for respiratory protection will vary according to the airborne concentrations and environmental conditions. A NIOSH approved air-purifying respirator with an organic vapor cartridge or canister may be permissible under certain circumstances. Consult the NIOSH web site (http://www.cdc.gov/niosh/npptl/topics/respirators/) for a list of respirator types and approved suppliers. |
| Other Protective: | Consult with local procedures for selection, training, inspection and maintenance of the personal protective equipment. |

EXPOSURE GUIDELINES

## SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

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| Physical State: | Liquid solution. |
| Boiling Point: | Approximately 100°C |
| Melting Point: | 207°C |
| Solubility: | Soluble. in water. |
| Vapor Density: | Not established. |
| Vapor Pressure: | Not established. |
| Percent Volatile: | Not established. |
| pH: | 3.8-5.9 |
| Molecular Formula: | Mixture |
| Molecular Weight: | 300.05 |
| Flash Point: | Not established. |
| Flash Point Method: | Not established. |
| Auto Ignition Temperature: | Not established. |

## SECTION 10 : STABILITY and REACTIVITY

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| Chemical Stability: | Stable under normal temperatures and pressures. |
| Hazardous Polymerization: | 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. |

## SECTION 11 : TOXICOLOGICAL INFORMATION

**Cisplatin :**

Acute Toxicity:

Acute LD50 SC Rat: 8100 mcg/kg
Acute LD50 SC Mouse: 16,900 mcg/kg
Acute LD50 SC Mouse: 13 mg/kg
Acute LD50 IV Rat: 8 mg/kg
Acute LD50 IV Mouse: 11 mg/kg
Acute LD50 Intramuscular Rat: 9200 mcg/kg
Acute LD50 Intramuscular Mouse: 7900 mcg/kg
Acute LD50 Mouse: 10,900 mcg/kg

**Cisplatin :**

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| IARC: | IARC: Group 2A: Probably carcinogenic to humans. |
| NTP: | NTP: Reasonably anticipated to be a human carcinogen. |
| Teratogenicity: | Pregnancy Category D: Cisplatin may cause fetal harm if administered to a pregnant woman. |

**Cisplatin :**

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| RTECS Number: | TP2450000 |
| Ingestion: | Oral - Rat LD50: 20 mg/kg [Kidney/Ureter/Bladder - Changes in tubules (including acute renal failure, acute tubular necrosis) Blood - Leukopenia Blood - changes in bone marrow (not otherwise specified)]<br>Oral - Rat LD50: 25800 ug/kg [Behavioral - Changes in motor activity (specific assay) Gastrointestinal - Hypermotility, diarrhea Blood - Normocytic anemia]<br>Oral - Mouse LD50: 32700 ug/kg [Lungs, Thorax, or Respiration - Cyanosis Gastrointestinal - Hypermotility, diarrhea Kidney/Ureter/Bladder - Urine volume increased]<br>Oral - Rat LD50: 25 mg/kg [Details of toxic effects not reported other than lethal dose value] |

**Sodium Chloride :**

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| RTECS Number: | VZ4725000 |
| Eye: | Eye - Rabbit Standard Draize test.: 10 mg [Moderate] |
| Skin: | Administration onto the skin - Rabbit LD50: >10 gm/kg [Details of toxic effects not reported other than lethal dose value]<br>Administration onto the skin - Rabbit Standard Draize test.: 50 mg/24H [mild]<br>Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H [mild] |
| Inhalation: | Inhalation - Rat LC50: >42 gm/m3/1H [Details of toxic effects not reported other than lethal dose value] |
| Ingestion: | Oral - Mouse LD50: 4 gm/kg [Details of toxic effects not reported other than lethal dose value]<br>Oral - Rat LD50: 3000 mg/kg [Details of toxic effects not reported other than lethal dose value] |

## SECTION 12 : ECOLOGICAL INFORMATION

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| Ecotoxicity: | No ecotoxicity data was found for the product. |
| Environmental Stability: | No environmental information found for this product. |

## SECTION 13 : DISPOSAL CONSIDERATIONS

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| Waste Disposal: | Dispose of in accordance with Local, State, Federal and Provincial regulations. |

## SECTION 14 : TRANSPORT INFORMATION

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| DOT Shipping Name: | Not Regulated. |
| DOT UN Number: | Not Regulated. |

## SECTION 15 : REGULATORY INFORMATION

**Cisplatin :**

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| TSCA Inventory Status: | Listed |
| EINECS Number: | 239-733-8 |
| California PROP 65: | Listed: cancer. |
| Canada DSL: | Listed |
| Canada IDL: | Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.495(629) |

**Sodium Chloride :**

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|---|---|
| TSCA Inventory Status: | Listed |
| EINECS Number: | 231-598-3 |
| Canada DSL: | Listed |

## SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

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|---|---|
| SDS Creation Date: | January 08, 2009 |
| SDS Revision Date: | June 10, 2015 |
| SDS Format: | |
| Disclaimer: | The information contained herein pertains to this material. It is the responsibility of each individual party to determine for themselves the proper means of handling and using these materials based on their purpose and intended use. Fresenius-Kabi assumes no liability resulting from the use of or reliance upon the information contained in this material safety data sheet. This material safety data sheet does not constitute the guaranty or specifications of the product. |

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