SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Carboplatin Injection**
Manufacturer Name:	Fresenius Kabi USA, LLC
Address:	Three Corporate Drive 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:
Respiratory sensitisation. Category 1.
Reproductive toxicity. Category 2.
Skin Sensitization. Category 1.
Acute Oral Toxicity. Category 4.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
Suspected of damaging fertility or the unborn child.
May cause an allergic skin reaction.
Harmful if swallowed.
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: Call a POISON CENTER or doctor/physician if you feel unwell.
IF ON SKIN: Wash with plenty of water.
IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.
IF exposed or concerned: Get medical advice/attention.
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.
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.
- Skin: May cause skin irritation.
- Inhalation: May cause irritation of respiratory tract.
- Ingestion: May cause irritation.

Signs/Symptoms: Side effects from therapeutic doses include: hematologic, gastrointestinal, neurologic, nephrotoxicity, hepatic toxicity, electrolyte changes, and allergic reactions. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions: History of severe allergic reactions to cisplatin or other platinum-containing compounds, mannitol, individuals with severe bone marrow suppression, or significant bleeding. May aggravate kidney disease, hearing disorders, neurological diseases, or bone marrow depression.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.

Carboplatin	41575-94-4	- %
Mannitol	69-65-8	- %
Water for Injection	7732-18-5	- %

SECTION 4 : FIRST AID MEASURES

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. 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

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. 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

Personnel Precautions:	Evacuate area and keep unnecessary and unprotected personnel from entering the spill area. 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

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 25°C (77°F); excursions permitted to 15 to 30°C (59 to 86°F). [See USP Controlled Room Temperature]. 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

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

Physical State:	Liquid solution.
Boiling Point:	Approximately 100°C
Melting Point:	Approximately 0°C
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	5 - 7 (1% Solution.)
Molecular Formula:	Mixture
Molecular Weight:	571.25
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.

SECTION 10 : STABILITY and REACTIVITY

Chemical Stability:	Stable under normal temperatures and pressures.
Hazardous Polymerization:	Not reported.
Conditions to Avoid:	Protect from light.
Incompatible Materials:	Avoid contact with aluminum.

SECTION 11 : TOXICOLOGICAL INFORMATION

Acute Toxicity:	Eye, skin, or respiratory tract irritation.
Carboplatin :	
Acute Toxicity:	Acute LD50 IV Rat: 61 mg/kg Acute LD50 IV Mouse: 89.36 mg/kg Acute LD50 IV Dog: > 31.2 mg/kg Acute LD50 IP Mouse: 150 mg/kg Acute LD50 SC Rat: 72 mg/kg
Acute Effects:	Eye, skin, or respiratory tract irritation.
Chronic Effects:	Possible hypersensitization. Carboplatin is a mutagen and possible carcinogen (carcinogenic potential has not been studies although similar mechanisms of action and mutagenicity profiles have been reported to be carcinogenic).
Teratogenicity:	Pregnancy Category D: Carboplatin may cause fetal harm when administered to pregnant women.
Carboplatin :	
RTECS Number:	TP2300000
Ingestion:	Oral - Rat LD50: 343 mg/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intravenous. - Rat LD50: 60900 ug/kg [Sense Organs and Special Senses (Eye) - effect, not otherwise specified Gastrointestinal - hypermotility, diarrhea Nutritional and Gross Metabolic - weight loss or decreased weight gain] Intravenous. - Mouse LD50: 89360 ug/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rat TDLo: 70 mg/kg/2W (intermittent) [Lungs, Thorax, or Respiration - changes in lung weight Endocrine - changes in spleen weight Blood - changes in platelet count] Intravenous. - Mouse TDLo: 162 mg/kg/5D (intermittent) [Gastrointestinal - other changes Blood - changes in bone marrow (not otherwise specified) Related to Chronic Data - death] Intravenous. - Human TDLo: 25 mg/kg/33D (intermittent) [Blood - leukopenia] Intravenous. - Human TDLo: 37.5 mg/kg/3D (intermittent) [Kidney/Ureter/Bladder - renal function tests depressed Blood - leukopenia] Intravenous. - Rat TDLo: 90 mg/kg/11D (intermittent) [Nutritional and Gross Metabolic - weight loss or

decreased weight gain]
Intravenous. - Mouse DNA damage: 128 mg/kg
Intravenous. - Mouse DNA inhibition: 60 mg/kg
Intravenous. - Mouse Cytogenetic analysis: 18800 ug/kg
Intravenous. - Rat TDLo: 24 mg/kg [Reproductive - Fertility - pre-implantation mortality (e.g. reduction in number of implants per female; total number of implants per corpora lutea) Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Effects on Embryo or Fetus - fetal death]
Intravenous. - Rat TDLo: 24 mg/kg [Reproductive - Specific Developmental Abnormalities - Central Nervous System Reproductive - Specific Developmental Abnormalities - body wall Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intravenous. - Rat TDLo: 12500 ug/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]
Subcutaneous - Rat LD50: 72 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse LD50: 118 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse TDLo: 25 mg/kg [Tumorigenic - protects against induction of experimental tumors]
Intraperitoneal. - Rat TDLo: 256 mg/kg [Sense Organs and Special Senses (Ear) - changes in cochlear structure or function Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - multiple enzyme effects]
Intraperitoneal. - Mouse TDLo: 100 mg/kg [Liver - other changes Tumorigenic - protects against induction of experimental tumors]
Intraperitoneal. - Mouse TDLo: 50 mg/kg [Liver - other changes]
Intraperitoneal. - Mouse TDLo: 32 mg/kg/5D (intermittent) [Blood - leukopenia]
Intraperitoneal. - Mouse TDLo: 100 mg/kg/5D (intermittent) [Liver - other changes Tumorigenic - protects against induction of experimental tumors]
Intraperitoneal. - Mouse TDLo: 90 mg/kg/9D (intermittent) [Tumorigenic - active as anti-cancer agent]
Intraperitoneal. - Mouse Micronucleus test: 75 mg/kg
Intraperitoneal. - Mouse Mutation test systems not otherwise specified: 75 mg/kg

Mannitol :

RTECS Number: OP2060000

Ingestion: Oral - Rat LD50: 13500 mg/kg [Details of toxic effects not reported other than lethal dose value]
Oral - Mouse LD50: 22 gm/kg [Behavioral - Somnolence (general depressed activity); Gastrointestinal - Ulceration or bleeding from small intestine]

Other Toxicological Information: Intravenous. - Rat LD50: 9690 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Mouse LD50: 7470 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse LD50: 14 gm/kg [Details of toxic effects not reported other than lethal dose value]

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity: No ecotoxicity data was found for the product.

Environmental Stability: No environmental information found for this product.

SECTION 13 : DISPOSAL CONSIDERATIONS

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

SECTION 14 : TRANSPORT INFORMATION

DOT Shipping Name: Not Regulated.

DOT UN Number: Not Regulated.

SECTION 15 : REGULATORY INFORMATION

State Regulations: Note:
This material contains carboplatin and is subject to the California Proposition 65 reproductive toxin warning and release requirements.

California PROP 65: This material contains carboplatin and is subject to the California Proposition 65 reproductive toxin warning and release requirements.

Carboplatin :

EINECS Number: 255-446-0

California PROP 65: Listed: developmental.

Mannitol :

TSCA Inventory Status: Listed

EINECS Number: 200-711-8

Canada DSL: Listed

Water for Injection :

TSCA Inventory Status: Listed

Canada DSL: Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	1
HMIS Fire Hazard:	1
HMIS Reactivity:	1
HMIS Personal Protection:	X

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Disclaimer:

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