SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Oxaliplatin 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 01, 2015

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:
Respiratory sensitisation. Category 1.
Reproductive toxicity. Category 2.
Skin Sensitization. Category 1.
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.
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 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).
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:
WARNING! The drug substance Oxaliplatin is mutagenic, cytotoxic, neurotoxic and fetotoxic. The drug substance is a possible carcinogen and a severe eye irritant. 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:
Anticipated signs of overexposure include nausea, vomiting, diarrhea, peripheral neurotoxicity (with cold sensitivity and rare laryngeal dysesthesias, sensation of difficulty with breathing or swallowing), and possible myelosuppression (low blood counts). Mucositis (sore mouth, or soreness of other mucous membranes) and transient elevation of liver enzymes have been observed. As with other platinum compounds allergic reactions have been observed. In therapeutic use very rare anaphylactoid reactions (severe, possibly life-threatening allergic reactions) have been observed.

Aggravation of Pre-Existing Conditions:
Individuals with a history of known allergy to oxaliplatin or other platinum compounds.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Succinic acid	110-15-6	0.01 mg /mL	
Sodium hydroxide	1310-73-2	0.0033 mg /mL	

Oxaliplatin	61825-94-3	5 mg /mL
Water for Injection	7732-18-5	Quantity sufficient to 1 mL

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 25ºC (77ºF); excursions permitted to 15 to 30ºC (59 to 86ºF). Protect from light. Do not freeze. Retain vial in carton until time of use.
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

Sodium hydroxide :

Guideline ACGIH:	TLV-Ceiling/Peak: 2 mg/m3
Guideline OSHA:	OSHA-TWA: 2 mg/m3

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	Colorless.
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	6 mg/mlin water. 20 °C
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	4.0-7.0
Molecular Formula:	Mixture
Molecular Weight:	397.3
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 freezing.

SECTION 11 : TOXICOLOGICAL INFORMATION

Succinic acid :

RTECS Number:	WM4900000
Eye:	Eye - Rabbit Standard Draize test.: 750 ug [severe]
Ingestion:	Oral - Rat LD50 : 2260 mg/kg [Details of toxic effects not reported other than lethal dose value]

Sodium hydroxide :

Eye:	Eye - Rabbit Standard Draize test.: 400 ug Eye - Rabbit Standard Draize test.: 50 ug/24H (RTECS)
Skin:	Administration onto the skin - Rabbit Standard Draize test.: 500 mg/24H

Oxaliplatin :

RTECS Number:	TP2275850
Ingestion:	LD50 Oral Rat: > 100 mg/kg
Carcinogenicity:	May be carcinogenic based on cytotoxic and genotoxic data.
Mutagenicity:	Positive genotoxic agent in both in vitro and in vivo tests. Oxaliplatin interacts with DNA, blocking DNA replication and transcription.
Reproductive Toxicity:	There was no impairment of fertility of treated rats. However, testicular hypoplasia has been detected in dogs following repeated doses of oxaliplatin.
Teratogenicity:	Oxaliplatin produced evidence of fetal toxicity in the rat but it was not teratogenic to the rat or rabbit. Pregnancy Category D: May cause harm when administered to a pregnant woman.
Other Toxicological Information:	Intravenous. - Human TDLo: 2.19 mg/kg [Nutritional and Gross Metabolic - body temperature increase] Intravenous. - Human TDLo: 2.125 mg/kg [Gastrointestinal - hypermotility, diarrhea Gastrointestinal - nausea or vomiting Immunological Including Allergic - other immediate (humoral): urticaria, allergic rhinitis, serum sickness]

Intravenous. - Human TDLo: 2.125 mg/kg [Cardiac - arrhythmias (including changes in conduction)]
Intravenous. - Human TDLo: 4.6 mg/kg/4W (intermittent) [Gastrointestinal - colon tumors Tumorigenic - active as anti-cancer agent]
Intravenous. - Mouse TDLo: 16 mg/kg/4D (intermittent) [Nutritional and Gross Metabolic - weight loss or decreased weight gain Tumorigenic - protects against induction of experimental tumors]
Intravenous. - Mouse TDLo: 21 mg/kg/4D (intermittent) [Nutritional and Gross Metabolic - weight loss or decreased weight gain Tumorigenic - protects against induction of experimental tumors Related to Chronic Data - death]
Intravenous. - Human TDLo: 5.14 mg/kg/74D (intermittent) [Lungs, Thorax, or Respiration - dyspnea Lungs, Thorax, or Respiration - other changes Immunological Including Allergic - other immediate (humoral): urticaria, allergic rhinitis, serum sickness]
Intravenous. - Human TDLo: 4.25 mg/kg/15D (intermittent) [Peripheral Nerve and Sensation - paresthesis]
Intravenous. - Human TDLo: 19.5 mg/kg/18W (intermittent) [Peripheral Nerve and Sensation - sensory change involving peripheral nerve]
Intravenous. - Human TDLo: 6.5 mg/kg/42D (intermittent) [Blood - granulocytopenia Blood - thrombocytopenia]
Intraperitoneal. - Rat LD50: 14300 ug/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse LD50: 19800 ug/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat TDLo: 3 mg/kg [Peripheral Nerve and Sensation - structural change in nerve or sheath]
Intraperitoneal. - Rat TDLo: 4.24 mg/kg [Spinal Cord - other degenerative changes]
Intraperitoneal. - Rat TDLo: 10 mg/kg [Spinal Cord - other degenerative changes Peripheral Nerve and Sensation - recording from afferent nerve]
Intraperitoneal. - Rat TDLo: 3 mg/kg [Peripheral Nerve and Sensation - sensory change involving peripheral nerve]
Intraperitoneal. - Mouse TDLo: 45 mg/kg/9D (intermittent) [Tumorigenic - active as anti-cancer agent]
Intraperitoneal. - Mouse TDLo: 25 mg/kg/5D (intermittent) [Tumorigenic - active as anti-cancer agent]

SECTION 12 : ECOLOGICAL INFORMATION

Biodegradation:	Hydrolysis test data indicate that Oxaliplatin will not readily hydrolyze in the environment.
Bioaccumulation:	The octanol / water partition coefficient (Kow) value of 0.02 indicates that Oxaliplatin is not likely to bioaccumulate. Dissociation constant (pKa) data indicate that oxaliplatin will not dissociate in the environmental pH range.
Mobility In Environmental Media:	Water Solubility, Kow and Henry's Law Constant data indicate that Oxaliplatin will migrate to the water compartment of the environment.

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

Risk Phrases:	R60 May impair fertility. R61 May cause harm to the unborn child. R64 May cause harm to breastfed babies. R68 Possible risk of irreversible effects. R40 Limited evidence of a carcinogenic effect. R42/43 May cause sensitization by inhalation and skin contact. R48/23/24/25 Toxic: danger of serious damage to health by prolonged exposure through inhalation, in contact with skin and if swallowed.
Safety Phrase:	S45 In case of accident or if you feel unwell, seek medical advice immediately (show the label where possible). S53 Avoid exposure — obtain special instructions before use.

Succinic acid :

TSCA Inventory Status:	Listed
Canada DSL:	Listed

Sodium hydroxide :

TSCA Inventory Status:	Listed
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	4*
HMIS Fire Hazard:	0
HMIS Reactivity:	0
HMIS Personal Protection:	X

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