SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Vinblastine Sulfate 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
(M)SDS Format:	

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:
Reproductive toxicity. Category 1A.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
May damage fertility or the unborn child.
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 contact during pregnancy and while nursing.
Wash hands thoroughly after handling.
Do not eat, drink or smoke when using this product.
Wear protective gloves/protective clothing/eye protection/face protection.
IF exposed or concerned: Get medical advice/attention.
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 reactions from therapeutic doses are generally related to the size of the dose employed. With the exception of epilation, leukopenia and neurologic side effects, adverse reactions generally have not persisted for longer than 24 hours. The most common adverse events are: leukopenia, alopecia, constipation, numbness of digits, hypertension, malaise, bone pain, weakness, pain in tumor-containing tissue, and jaw pain. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions:
Individuals with significant granulocytopenia unless this is a result of the disease being treated or individuals with bacterial infections.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Vinblastine Sulfate	143-67-9	1 mg/mL	
Sodium Chloride	7647-14-5	9 mg/mL	
Benzyl Alcohol	100-51-6	- % Amount: 0.9% (v/v) by Volume	
Water for Injection	7732-18-5	Quantity Sufficient	

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 refrigerated temperatures 2 to 8°C (36 to 46°F). Protect from light. 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

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	Colorless.
Odor:	Odorless.
Boiling Point:	Not established.
Melting Point:	284 - 285°C
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	3.5 - 5.0
Molecular Formula:	Mixture
Molecular Weight:	909.06
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:	Exposure to light or heat may cause decomposition.

SECTION 11 : TOXICOLOGICAL INFORMATION

Vinblastine Sulfate :

Acute Toxicity:

LD50 IV Rat: 37 mg/kg
LD50 IP Rat: 1 mg/kg
LD50 SC Rat: 355 mg/kg
LD50 IV Mouse: 15 mg/kg
LD50 IP Mouse: 27 mg/kg
LD50 SC Mouse: 324 mg/kg

Vinblastine Sulfate :

IARC: IARC: Group 3: Unclassifiable as to carcinogenicity to humans.

Teratogenicity: Pregnancy Category D:
Caution is necessary with the administration of all oncolytic drugs during pregnancy. Information on the use of vinblastine sulfate during human pregnancy is very limited. Animal studies with vinblastine sulfate suggest that teratogenic effects may occur.

Vinblastine Sulfate :

RTECS Number: YY8400000

Ingestion: Oral - Rat LD50: 305 mg/kg [Details of toxic effects not reported other than lethal dose value]
Oral - Mouse LD50: 423 mg/kg [Details of toxic effects not reported other than lethal dose value]

Other Toxicological Information: Intravenous. - Human TDLo: 557 ug/kg [Blood - leukopenia Skin and Appendages - hair]
Intravenous. - Rat LD50: 37 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Mouse LD50: 9500 ug/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Mouse TDLo: 12.2 mg/kg [Peripheral Nerve and Sensation - structural change in nerve or sheath Sense Organs and Special Senses (Olfaction) - effect, not otherwise specified]
Intravenous. - Rabbit TDLo: 500 ug/kg [Reproductive - Fertility - other measures of fertility]
Subcutaneous - Rat LD50: 355 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Mouse LD50: 324 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Mouse TDLo: 4 mg/kg/2D (intermittent) [Skin and Appendages - dermatitis, other (after systemic exposure)]
Subcutaneous - Guinea pig TDLo: 200 ug/kg/2D (intermittent) [Skin and Appendages - dermatitis, other (after systemic exposure)]
Subcutaneous - Mouse TDLo: 10 mg/kg [Reproductive - Specific Developmental Abnormalities - craniofacial (including nose and tongue) Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Rat LD50: 1 mg/kg [Behavioral - somnolence (general depressed activity) Gastrointestinal - hypermotility, diarrhea]
Intraperitoneal. - Mouse LD50: 2700 ug/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat TDLo: 3 mg/kg/15D (intermittent) [Gastrointestinal - other changes Blood - leukopenia Related to Chronic Data - death]
Intraperitoneal. - Rat TDLo: 3500 ug/kg/2W (intermittent) [Liver - changes in liver weight Blood - normocytic anemia Related to Chronic Data - death]
Intraperitoneal. - Mouse TDLo: 350 ug/kg [Reproductive - Specific Developmental Abnormalities - eye/ear Reproductive - Specific Developmental Abnormalities - body wall Reproductive - Specific Developmental Abnormalities - musculoskeletal system]

Intraperitoneal. - Mouse TDLo: 250 ug/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]
Intraperitoneal. - Mouse TDLo: 50 ug/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)]
Intraperitoneal. - Mouse TDLo: 350 ug/kg [Reproductive - Effects on Embryo or Fetus - cytological changes (including somatic cell genetic material)]
Intraperitoneal. - Rat Micronucleus test: 200 ug/kg
Intraperitoneal. - Rat DNA inhibition: 1 mg/kg
Intraperitoneal. - Rat Sperm Morphology: 555 ug/kg
Intraperitoneal. - Mouse Micronucleus test: 10 ug/kg
Intraperitoneal. - Mouse Mutation test systems : 230 ug/kg
Intraperitoneal. - Mouse Mutation test systems : 1 mg/kg
Intraperitoneal. - Mouse Sex chromosome loss and nondisjunction: 230 ug/kg
Intraperitoneal. - Mouse Sperm Morphology: 5 mg/kg/5D
Intraperitoneal. - Rat Cytogenetic analysis: 1 mg/kg/2D
Intraperitoneal. - Rat Micronucleus test: 0.24 mg/kg/4D

Sodium Chloride :

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]
Administration onto the skin - Rabbit Standard Draize test.: 50 mg/24H [mild]
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]
Oral - Rat LD50: 3000 mg/kg [Details of toxic effects not reported other than lethal dose value]

Other Toxicological Information: Intravenous. - Mouse LD50: 645 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Rabbit LDLo: 1100 mg/kg [Behavioral - convulsions or effect on seizure threshold Behavioral - muscle contraction or spasticity Cardiac - other changes]
Intravenous. - Guinea pig LDLo: 300 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Mouse TDLo: 2.1 mg/kg [Vascular - other changes Blood - hemorrhage Skin and Appendages - dermatitis, irritative (after systemic exposure)]
Intravenous. - Rabbit LDLo: 1.5 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intravenous. - Rabbit TDLo: 0.04 mg/kg [Vascular - other changes Blood - hemorrhage Skin and Appendages - dermatitis, irritative (after systemic exposure)]
Subcutaneous - Rat LDLo: 3500 mg/kg [Behavioral - irritability]
Subcutaneous - Mouse LD50: 3 gm/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Guinea pig LDLo: 2160 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Rabbit TDLo: 0.04 mg/kg [Vascular - other changes Skin and Appendages - dermatitis, irritative (after systemic exposure)]
Subcutaneous - Mouse TDLo: 1900 mg/kg [Reproductive - Effects on Embryo or Fetus - fetal death]
Subcutaneous - Mouse TDLo: 1900 mg/kg [Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Subcutaneous - Mouse TDLo: 2500 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]
Subcutaneous - Mouse TDLo: 13440 mg/kg [Reproductive - Fertility - abortion]
Intraperitoneal. - Mouse LD50: 2602 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat LD50: 2600 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Rat LDLo: 3.72 gm/kg [Behavioral - tremor Behavioral - convulsions or effect on seizure threshold]
Intraperitoneal. - Rat TDLo: 1710 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Effects on Embryo or Fetus - fetal death Reproductive - Specific Developmental Abnormalities - musculoskeletal system]
Intraperitoneal. - Rat TDLo: 10 gm/kg [Reproductive - Effects on Newborn - behavioral]
Intraperitoneal. - Rat Cytogenetic analysis: 2338 mg/kg

Benzyl Alcohol :

RTECS Number: DN3150000

Skin: Administration onto the skin - Rabbit LD50: 2000 mg/kg [Details of toxic effects not reported other than lethal dose value]
Administration onto the skin - Rabbit Standard Draize test.: 100 mg/24H
Administration onto the skin - Rat LD50: 100 pph/90M [Details of toxic effects not reported other than lethal dose value]

Inhalation: Inhalation - Mouse LC50: >500 mg/m3 [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax, or Respiration - Respiratory depression]
Inhalation - Rat LC50: >500 mg/m3 [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax, or Respiration - Respiratory depression]

Ingestion: Oral - Rat LD50: 1230 mg/kg [Behavioral - Somnolence (general depressed activity) Behavioral - Excitement Behavioral - Coma]
Oral - Mouse LD50: 1360 mg/kg [Details of toxic effects not reported other than lethal dose value]
Oral - Mouse LD50: 1360 mg/kg [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax, or Respiration - Respiratory depression]
Oral - Rat LD50: 1660 mg/kg [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax, or Respiration - Respiratory depression]
Oral - Rat LD50: 1.5 mL/kg [Details of toxic effects not reported other than lethal dose value]

Other Toxicological Information: Intravenous. - Rat LD50: 53 mg/kg [Lungs, Thorax, or Respiration - dyspnea]
Intravenous. - Mouse LD50: 324 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Rat LDLo: 1700 mg/kg [Sense Organs and Special Senses (Eye) - miosis (pupillary constriction) Behavioral - coma Kidney/Ureter/Bladder - other changes]
Intraperitoneal. - Rat LD50: 400 mg/kg [Details of toxic effects not reported other than lethal dose value]
Intraperitoneal. - Mouse LD50: 650 mg/kg [Behavioral - altered sleep time (including change in righting reflex) Behavioral - somnolence (general depressed activity) Lungs, Thorax, or Respiration - dyspnea]
Intraperitoneal. - Rat LDLo: 650 mg/kg [Behavioral - somnolence (general depressed activity) Behavioral - ataxia Lungs, Thorax, or Respiration - respiratory depression]
Intraperitoneal. - Rat TDLo: 514 mg/kg [Behavioral - ataxia]

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

Vinblastine Sulfate :

EINECS Number:	205-606-0
California PROP 65:	Listed: developmental.

Sodium Chloride :

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

Benzyl Alcohol :

TSCA Inventory Status:	Listed
EINECS Number:	202-859-9
Canada DSL:	Listed
Canada IDL:	Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.169(170)

Water for Injection :

TSCA Inventory Status:	Listed
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

SDS Creation Date:	January 08, 2009
SDS Revision Date:	June 01, 2015
SDS Format:	
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