SECTION 1 : PRODUCT AND COMPANY IDENTIFICATION

Product Name:	**Bacteriostatic Sodium Chloride Injection, USP**
Manufacturer Name:	Fresenius Kabi Canada Ltd.
Address:	45 Vogell Road Suite 200 Richmond Hill, Ontario L4B 3P6 Canada
General Phone Number:	905-770-3711
CHEMTREC:	800-424-9300 (24 hours everyday).
Canutec:	(613) 996-6666 (Canada 24 hours everyday).

HMIS

Health Hazard	1
Fire Hazard	1
Reactivity	1
Personal Protection	X

SECTION 2 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Sodium Chloride	7647-14-5	9 mg/mL	
Benzyl Alcohol	100-51-6	0.9 %	
Methylparaben	99-76-3	0.12 %	
Propylparaben	94-13-3	0.012 %	
Water for Injection	7732-18-5	- Quantity Sufficient. -	

Note:

SECTION 3 : HAZARDS IDENTIFICATION

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:	Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Side effects from therapeutic doses may include: Febrile response, local tenderness, abscess, tissue necrosis, infection at the site of injection, venous thrombosis, phlebitis extending from the site of injection, and extravasation. Occupational exposure has not been fully investigated.
Aggravation of Pre-Existing Conditions:	No medical conditions are known to be aggravated by accidental exposure.

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 Vigilance: (905) 770-3711.

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

Personal 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 controlled room temperature 20 to 25°C (68 to 77°F). [See USP Controlled Room Temperature].
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 - EXPOSURE GUIDELINES

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

Ingredient	Guideline OSHA	Guideline ACGIH	Quebec Canada	Ontario Canada	Alberta Canada
Sodium Chloride	Not established.	Not established.	Not established.	Not established.	Not established.
Benzyl Alcohol	Not established.	Not established.	Not established.	Not established.	Not established.
Methylparaben	Not established.	Not established.	Not established.	Not established.	Not established.
Propylparaben	Not established.	Not established.	Not established.	Not established.	Not established.
Water for Injection	Not established.	Not established.	Not established.	Not established.	Not established.

Ingredient	British Columbia Canada
Sodium Chloride	Not established.
Benzyl Alcohol	Not established.
Methylparaben	Not established.
Propylparaben	Not established.
Water for Injection	Not established.

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid.
Color:	Colorless.
Odor:	Odorless.
Boiling Point:	Not established.
Melting Point:	Not established.
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	4.5 - 7.0
Molecular Formula:	Mixture
Molecular Weight:	58.44
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:	No conditions contributing to instability are known to exist for normal handling of this product.

SECTION 11 : TOXICOLOGICAL INFORMATION

Sodium Chloride :

RTECS Number:	VZ4725000
Eye:	Administration into the eye - Rabbit Standard Draize test: 100 mg/24H [Moderate] Administration into the eye - Rabbit Standard Draize test: 10 mg [Moderate] (RTECS)
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 - Rat LD50 - Lethal dose, 50 percent kill: 3000 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)
Other Toxicological Information:	Intravenous. - Mouse LD50: 645 mg/kg [Details of toxic effects not reported other than lethal dose value] 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] Subcutaneous - Mouse LD50: 3 gm/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

Benzyl Alcohol :

RTECS Number:	DN3150000
Skin:	Administration onto the skin - Rabbit LD50 - Lethal dose, 50 percent kill: 2000 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)
Inhalation:	Inhalation - Rat LC50 - Lethal concentration, 50 percent kill: >500 mg/m3 [Behavioral-Somnolence (general depressed activity)Behavioral-AtaxiaLungs, Thorax, or Respiration-Respiratory depression] (RTECS)
Ingestion:	Oral - Rat LD50 - Lethal dose, 50 percent kill: 1230 mg/kg [Behavioral-Somnolence (general depressed activity)Behavioral-ExcitementBehavioral-Coma] Oral - Rat LD50 - Lethal dose, 50 percent kill: 1660 mg/kg [Behavioral-Somnolence (general depressed activity)Behavioral-AtaxiaLungs, Thorax, or Respiration-Respiratory depression] Oral - Rat LD50 - Lethal dose, 50 percent kill: 1.5 mL/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)
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] 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] (RTECS)

Methylparaben :

RTECS Number:	DH2450000
Skin:	Administration onto the skin - Rabbit Standard Draize test.: 0.1 mL/24H Administration onto the skin - Rabbit Standard Draize test.: 0.5 mL/21D (Intermittent) Administration onto the skin - Rat TDLo: 374.92 gm/kg/13W (Intermittent) [Nutritional and Gross Metabolic - Weight loss or decreased weight gain Blood - Other changes]
Ingestion:	Oral - Rat LD50 - Lethal dose, 50 percent kill: 2100 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)
Other Toxicological Information:	Intraperitoneal. - Rat LD50: 960 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse LD50: 125 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse LD50: 960 mg/kg [Peripheral Nerve and Sensation - Flaccid paralysis without anesthesia (usually neuromuscular blockage) Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia] Subcutaneous - Mouse LD50: 1.2 gm/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rat LD50: >500 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

Propylparaben :

RTECS Number:	DH2800000
Ingestion:	Oral - Mouse LD50: 6332 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)
Other Toxicological Information:	Intraperitoneal. - Mouse LD50: 200 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse LD50: 1650 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS)

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

Canada Reg. Status:	This product has been classified in accordance with the hazard criteria of the Controlled Products Regulations and the MSDS contains all of the information required by the Controlled Products Regulations.
Canada WHMIS:	Controlled - Class: D2B Toxic

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)

Methylparaben :

TSCA Inventory Status:	Listed
EINECS Number:	202-785-7
Canada DSL:	Listed

Propylparaben :

TSCA Inventory Status:	Listed
EINECS Number:	202-307-7
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

SDS Creation Date:	January 15, 2011
SDS Revision Date:	April 07, 2015
MSDS Revision Notes:	Manufacturer name and logo change.
SDS Format:	

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