SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Gentamicin Injection, USP**
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:
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:
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.

Chronic Health Effects: Hypersensitivity reactions ranging from mild to severe may occur.

Signs/Symptoms:
Potential adverse reactions from prescribed doses and overdoses are described in the package insert. Side effects from therapeutic doses include: nephrotoxicity, neurotoxicity (dizziness, vertigo, tinnitus, hearing loss), respiratory depression, lethargy, confusion, visual disturbances, headache, nausea, vomiting, and laboratory abnormalities. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions:
History of hypersensitivity or serious toxic reactions to aminoglycosides. Preserved gentamicin injection contains sodium metabisulfite. Sulfites may cause allergic-type reactions including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.

Gentamicin Sulfate	1405-41-0	10 mg/mL or 40 mg/mL
Methylparaben	99-76-3	- %
Propylparaben	94-13-3	0.2 mg/mL in preserved product
Edetate Disodium	139-33-3	0.1 mg/mL in preserved product
Sodium Metabisulfite	7681-57-4	3.2 mg/mL in preserved product
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 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

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:	Not established.
Melting Point:	218 to 237 °C
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
pH:	3.0 - 5.5
Molecular Formula:	Mixture
Molecular Weight:	Not established.
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

Gentamicin Sulfate :

RTECS Number:	LY2625000
Inhalation:	LC50: Inhalation Rat > 0.2 mg/L
Ingestion:	Oral - Rat LD50: >5 gm/kg [Behavioral - Somnolence (general depressed activity) Skin and Appendages - Hair] Oral - Mouse LD50: >11269 mg/kg [Details of toxic effects not reported other than lethal dose value]
Other Toxicological Information:	Intraperitoneal. - Rat TDLo: 480 mg/kg/6D (Intermittent) [Kidney/Ureter/Bladder - Changes in tubules (including acute renal failure, acute tubular necrosis) Kidney/Ureter/Bladder - Other changes Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - Catalases] Intraperitoneal. - Rat TDLo: 560 mg/kg/7D (Intermittent) [Kidney/Ureter/Bladder - Changes in both tubules and glomeruli Kidney/Ureter/Bladder - Renal function tests depressed Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - Catalases] Intraperitoneal. - Rat TDLo: 375 mg/kg [Reproductive - Specific Developmental Abnormalities - Urogenital system Reproductive - Effects on Newborn - growth statistics (e.g.,%, reduced weight gain)] Intraperitoneal. - Rat TDLo: 400 mg/kg/5D (Continuous) [Gastrointestinal - Other changes Kidney/Ureter/Bladder - Renal function tests depressed Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - Dehydrogenases] Intraperitoneal. - Rat TDLo: 720 mg/kg/9D (Continuous) [Gastrointestinal - Other changes Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - Catalases Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - Other oxidoreductases] Intraperitoneal. - Mouse LD50: 245 mg/kg [Behavioral - Altered sleep time (including change in righting reflex) Behavioral - Convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - Respiratory stimulation] Intraperitoneal. - Rat LD50: 630 mg/kg [Behavioral - Muscle contraction or spasticity Lungs, Thorax, or Respiration - Other changes] Intraperitoneal. - Rat TDLo: 700 mg/kg/7D (Intermittent) [Kidney/Ureter/Bladder - Changes in tubules (including acute renal failure, acute tubular necrosis) Kidney/Ureter/Bladder - Urine volume increased Blood - Changes in serum composition (e.g., TP, bilirubin, cholesterol)] Intraperitoneal. - Rat TDLo: 600 mg/kg/6D (Intermittent) [Kidney/Ureter/Bladder - Changes in tubules

(including acute renal failure, acute tubular necrosis) Blood - Changes in serum composition (e.g., TP, bilirubin, cholesterol) Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - Multiple enzyme effects]
Intraperitoneal. - Rat DNA damage: 70 mg/kg/7D (Continuous)
Intraperitoneal. - Rat TDLo: 560 mg/kg/7D (Intermittent) [Kidney/Ureter/Bladder - Changes in both tubules and glomeruli Kidney/Ureter/Bladder - Renal function tests depressed Biochemical - Metabolism (Intermediary) - Lipids including transport]
Intravenous. - Mouse LD50: 47 mg/kg [Behavioral - Somnolence (general depressed activity) Behavioral - Convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - Dyspnea]
Intravenous. - Rat LD50: 96 mg/kg [Behavioral - Altered sleep time (including change in righting reflex) Behavioral - Convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - Respiratory stimulation]
Subcutaneous - Rat TDLo: 660 mg/kg [Reproductive - Effects on Newborn - Biochemical and metabolic]
Subcutaneous - Rat TDLo: 660 mg/kg [Reproductive - Specific Developmental Abnormalities - Cardiovascular (circulatory) system Reproductive - Specific Developmental Abnormalities - Urogenital system]
Subcutaneous - Mouse LD50: 478 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Rat TDLo: 1200 mg/kg/3D (Intermittent) [Kidney/Ureter/Bladder - Renal function tests depressed Kidney/Ureter/Bladder - Other changes Biochemical - Metabolism (intermediary) - Other proteins]
Subcutaneous - Rat LD50: 873 mg(base)/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Rat TDLo: 1200 mg/kg/15D (Intermittent) [Kidney/Ureter/Bladder - Changes in tubules (including acute renal failure, acute tubular necrosis) Kidney/Ureter/Bladder - Proteinuria Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - Dehydrogenases]
Subcutaneous - Rat TDLo: 200 mg/kg/5D (Intermittent) [Kidney/Ureter/Bladder - Other changes in urine composition Nutritional and Gross Metabolic - Changes in calcium Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - Other Enzymes]
Subcutaneous - Rat TDLo: 280 mg(base)/kg/7D (Intermittent) [Kidney/Ureter/Bladder - Other changes in urine composition Nutritional and Gross Metabolic - Changes in calcium Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - Dehydrogenases]
Subcutaneous - Rat TDLo: 300 mg/kg/3D (Intermittent) [Kidney/Ureter/Bladder - Other changes in urine composition Kidney/Ureter/Bladder - Other changes Biochemical - Metabolism (Intermediary) - Other proteins]
Subcutaneous - Guinea pig TDLo: 6557 mg/kg/77D (Intermittent) [Sense Organs and Special Senses (Ear) - Change in acuity Sense Organs and Special Senses (Ear) - Changes in cochlear structure or function Behavioral - Muscle contraction or spasticity]
Subcutaneous - Guinea pig LD50: 600 mg/kg [Details of toxic effects not reported other than lethal dose value]

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 - Mouse LD50: >8 gm/kg [Peripheral Nerve and Sensation - Flaccid paralysis without anesthesia (usually neuromuscular blockage) Behavioral - Ataxia]
Oral - Mouse LD50: >8000 mg/kg [Behavioral - Ataxia]
Oral - Rat LD50: 2100 mg/kg [Details of toxic effects not reported other than lethal dose value]

Other Toxicological Information: Intravenous. - Mouse TDLo: 100 mg/kg [Vascular - Shock Lungs, Thorax, or Respiration - Respiratory depression]
Intravenous. - Mouse TDLo: 2.5 mg/kg [Lungs, Thorax, or Respiration - Tumors]
Subcutaneous - Mouse TDLo: 165 mg/kg/3D (Intermittent) [Reproductive - Maternal Effects - Uterus, cervix, vagina Related to Chronic Data - Changes in uterine weight]
Subcutaneous - Mouse TDLo: 165 mg/kg [Behavioral - Ataxia Lungs, Thorax, or Respiration - Respiratory depression]
Subcutaneous - Rat LD50: >500 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Mouse TDLo: 49.5 mg/kg/3D (Intermittent) [Related to Chronic Data - Changes in uterine weight]
Subcutaneous - Mouse LD50: 1.2 gm/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]
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]

Propylparaben :

RTECS Number: DH2800000

Ingestion: Oral - Mouse LD50: 6332 mg/kg [Details of toxic effects not reported other than lethal dose value]

Other Toxicological Information: Subcutaneous - Mouse LD50: 1650 mg/kg [Details of toxic effects not reported other than lethal dose value]
Subcutaneous - Mouse TDLo: 195 mg/kg/3D (Intermittent) [Reproductive - Maternal Effects - Uterus, cervix, vagina Related to Chronic Data - Changes in uterine weight]
Subcutaneous - Rat TDLo: 99 mg/kg/3D (Intermittent) [Related to Chronic Data - Changes in uterine weight]
Subcutaneous - Mouse TDLo: 51 mg/kg/3D (Intermittent) [Related to Chronic Data - Changes in uterine weight]
Intraperitoneal. - Mouse LD50: 200 mg/kg [Details of toxic effects not reported other than lethal dose value]

Edetate Disodium :

RTECS Number: AH4375000

Eye: Rabbit, not irritating.

Skin: Rabbit, not irritating.

Inhalation: Inhalation - Rat LOAEC 30 mg/m³/6 h (aerosol) (OECD Guideline 412) (ECHA)

Ingestion: Oral - Rat LD50 2800 mg/kg (ECHA)

Other Toxicological Information: Intravenous. - Mouse LD50: 56 mg/kg (RTEC)

Sodium Metabisulfite :

RTECS Number: UX8225000

Eye: Rabbit, Irritating.

Skin:	Dermal - Rat LD50 : > 2000 mg/kg (TS : Sodium sulfite) (ECHA) Rabbit, Not irritating.
Inhalation:	Inhalation - Rat LC50 : > 5.5 mg/L/4 h (dust/aerosol) (TS : Sodium sulfite) (ECHA)
Ingestion:	Oral - Rat LD50: 1540 mg/kg (OECD SIDS)
Other Toxicological Information:	Intravenous. - Rat LD50: 115 mg/kg Intravenous. - Rabbit LDLo: 192 mg/kg (RTEC)

SECTION 12 : ECOLOGICAL INFORMATION

Ecotoxicity:	No ecotoxicity data was found for the product.
Environmental Stability:	No environmental information found for this product.
Edetate Disodium :	
Ecotoxicity:	Guppy (Poecilia reticulata) LC50 (96hr) 320 mg/L (OECD SIDS) Zebra fish (Danio rerio) NOEC (35d) >= 25.7 mg/L (OECD Guideline 210 , GLP) (TS : Ethylenediamintetraacetic acid, calcium disodium complex) Water flea (Daphnia magna) EC50 (48hr) 140 mg/L, NOEC (21d) 25 mg/L (EEC Guideline XI/681/86, GLP) (TS : Ethylenediaminetetraacetic acid, disodium salt) Green algae (Scenedesmus quadricauda) NOEC (24 d) 200 mg/L (ECHA)
Sodium Metabisulfite :	
Ecotoxicity:	Japanese rice fish (Oryzias latipes) LC50 (96 hr) >100 mg/L (OECD TG 203) Water flea (Daphnia magna) EC50 (48 hr) = 88.76 mg/L, NOEC (21d) > 10 mg/L (OECD TG 211) Green algae (Scenedesmus subspicatus) OECD TG 201 EC50 (72 hr) =48.1mg/L (OECD SIDS)

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

EINECS Number:	215-778-9
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
Edetate Disodium :	
TSCA Inventory Status:	Listed
EINECS Number:	205-358-3
Canada DSL:	Listed
Sodium Metabisulfite :	
TSCA Inventory Status:	Listed
EINECS Number:	231-673-0
Canada DSL:	Listed
Canada IDL:	Identified under the Canadian Hazardous Products Act Ingredient Disclosure List: 0.1%.1447(1083)
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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