SAFETY DATA SHEET

SECTION 1 : IDENTIFICATION

Product Name:	**Tobramycin 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:	November 10, 2023

SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

Signal Word: DANGER.

GHS Class:
Serious Eye Damage. category 1.
Respiratory sensitisation. category 1.
Reproductive toxicity. Category 1A.
Skin Irritation. Category 2.
Skin Sensitization. category 1.
Reproductive toxicity. Effects on or via lactation.

Hazard Statements:
Causes serious eye damage.
May cause allergy or asthma symptoms or breathing difficulties if inhaled.
May damage fertility or the unborn child.
Causes skin irritation.
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 IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing.
IF exposed or concerned: Get medical advice/attention.
Immediately call a POISON CENTER or doctor/physician.
Specific treatment (see ... on this label).
If skin irritation occurs: Get medical advice/attention.
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.

Signs/Symptoms: The severity of the signs and symptoms following a tobramycin overdose are dependent of the dose administered, the patient's renal function, state of hydration, and age and whether or not other medications with similar toxicities are being administered concurrently. Side effects from therapeutic doses include neurotoxicity (auditory and vestibular ototoxicity), nephrotoxicity, hematologic toxicity (anemia, granulocytopenia, etc), and laboratory abnormalities. Occupational exposure has not been fully investigated.

Aggravation of Pre-Existing Conditions: Individuals with a history of previous hypersensitivity or toxic reaction to any aminoglycoside. This product contains sodium metabisulfite, a sulfite that may cause allergic-type reactions, including anaphylactic symptoms and life-threatening or less severe asthmatic episodes in certain susceptible people. Concurrent and sequential use of other neurotoxic and/or nephrotoxic antibiotics particularly other aminoglycosides (amikacin, gentamicin, etc), polymyxin B, colistin, cisplatin, and vancomycin should be avoided. Other factors that may increase risk are advanced age and dehydration.

SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

Chemical Name	CAS#	Ingredient Percent	EC Num.
Tobramycin Sulfate	32986-56-4	Available as 10 mg/mL and 40 mg/mL	
Phenol	108-95-2	5 %	
Sodium Metabisulfite	7681-57-4	3.2 mg/mL	
Edetate Disodium	139-33-3	0.1 mg/mL	
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

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

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

Phenol :

Guideline OSHA:	Skin: Yes.

SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

Physical State:	Liquid solution.
Color:	Colorless.
Odor:	No information.
Odor Threshold:	No information.
Boiling Point:	Approximately 100°C
Melting Point:	Approximately 0°C
Density:	Not available.
Specific Gravity:	No information.
Specific Volume:	No information.
Solubility:	Soluble. in water.
Vapor Density:	Not established.
Vapor Pressure:	Not established.
Percent Volatile:	Not established.
Evaporation Rate:	No information.
pH:	3.0-6.5
Molecular Formula:	Mixture
Molecular Weight:	1425.45
Viscosity:	No information.
Coefficient of Water/Oil Distribution:	No information.
Flash Point:	Not established.
Flash Point Method:	Not established.
Auto Ignition Temperature:	Not established.
VOC Content:	No information.

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

Tobramycin Sulfate :

Acute Toxicity:	Acute Toxicity: LD50 SC Rat: 1,680 mg/kg LD50 IV Rat: 126 mg/kg LD50 IP Mouse: 262 mg/kg LD50 SC Mouse: 560 mg/kg LD50 IV Mouse: 77 mg/kg

Phenol :

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

Tobramycin Sulfate :

RTECS Number:	WK2100000
Ingestion:	Oral - Rat LD50 : >7500 mg/kg (RTEC)
Other Toxicological Information:	Intravenous. - Rat LD50 : 104 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Mouse LD50 : 72500 ug/kg [Behavioral - convulsions or effect on seizure threshold Behavioral - ataxia Lungs, Thorax, or Respiration - dyspnea] Intravenous. - Mouse LD50 : 70 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rat LD50 : 969 mg/kg [Sense Organs and Special Senses (Olfaction) - effect, not otherwise specified] Subcutaneous - Mouse LD50 : 367 mg/kg [Sense Organs and Special Senses (Eye) - ptosis Behavioral - somnolence (general depressed activity) Lungs, Thorax, or Respiration - respiratory depression] Subcutaneous - Rat TDLo : 1200 mg/kg/10D-I [Kidney/Ureter/Bladder - changes in tubules (including acute renal failure, acute tubular necrosis) Blood - changes in serum composition (e.g. TP, bilirubin, cholesterol)] Subcutaneous - Rat TDLo : 560 mg/kg/14D-I [Kidney/Ureter/Bladder - other changes in urine composition] Subcutaneous - Rat TDLo : 3250 mg/kg/65D-I [Sense Organs and Special Senses (Eye) - effect, not otherwise specified Sense Organs and Special Senses (Ear) - changes in vestibular functions Blood - changes in serum composition (e.g. TP, bilirubin, cholesterol)] Subcutaneous - Guinea pig TDLo : 1072 mg/kg/16D-I [Sense Organs and Special Senses (Ear) - changes in cochlear structure or function] Intraperitoneal. - Rat LD50 : 1030 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse LD50 : 445 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat TDLo : 800 mg/kg/10D-I [Kidney/Ureter/Bladder - other changes Biochemical - Enzyme inhibition, induction, or change in blood or tissue levels - other Enzymes Biochemical - Metabolism (Intermediary) - other] Intraperitoneal. - Rat TDLo : 800 mg/kg/4D-I [Kidney/Ureter/Bladder - changes in tubules (including acute renal failure, acute tubular necrosis) Blood - changes in serum composition (e.g. TP, bilirubin, cholesterol) Nutritional and Gross Metabolic - weight loss or decreased weight gain] Intraperitoneal. - Rat TDLo : 600 mg/kg [Reproductive - Effects on Newborn - physical]

Phenol :

RTECS Number:	SJ3325000
Eye:	Phenol is corrosive to the rabbit eye.
Skin:	Dermal - Rat LD50 : 660-707 mg/kg (OECD SIDS) Phenol causes severe chemical burns. Prolonged and/or repeated skin contact with this product may cause damage to epidermal tissue.
Inhalation:	Inhalation - Rat LC0 : 900 mg/m³/8 h (ECHA) Prolonged and/or repeated inhalation may cause damage to liver. This product if inhaled may cause upper respiratory irritation and possible central nervous system effects including headaches, nausea, vomiting, dizziness, drowsiness, loss of coordination, impaired judgement, and general weakness.
Ingestion:	Oral - Rat LD50: 340 mg/kg (OECD SIDS) Prolonged and/or repeated oral exposure may cause damage to nervous system.
Mutagenicity:	Phenol should be regarded as a somatic cell mutagen.
Other Toxicological Information:	Intravenous. - Mouse LD50: 112 mg/kg [Behavioral - tremor] Intravenous. - Rabbit LDLo: 180 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Mouse LD50: 344 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rabbit LDLo: 620 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Guinea pig LDLo: 450 mg/kg [Details of toxic effects not reported other than lethal dose value] Subcutaneous - Rat LD50: 300 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rat LD50: 127 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse LD50: 180 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Rabbit LDLo: 620 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Guinea pig LDLo: 300 mg/kg [Details of toxic effects not reported other than lethal dose value] Intraperitoneal. - Mouse TDLo: 300 mg/kg [Nutritional and Gross Metabolic - body temperature decrease] Intraperitoneal. - Mouse TDLo: 300 mg/kg [Immunological Including Allergic - hypersensitivity delayed] Intraperitoneal. - Rat TDLo: 650 mg/kg/17D (intermittent) [Blood - other changes] Intraperitoneal. - Mouse Micronucleus test: 265 mg/kg Intraperitoneal. - Rat TDLo: 600 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus)]

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)

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. - Rabbit TDLo : 300 mg/kg/30D-I [Liver - other changes Kidney/Ureter/Bladder - other changes Endocrine - other changes] Intravenous. - Mouse LD50 : 56 mg/kg [Details of toxic effects not reported other than lethal dose value] Intravenous. - Rabbit LD50 : 47 mg/kg [Behavioral - convulsions or effect on seizure threshold] Subcutaneous - Rat TDLo : 380 mg/kg [Reproductive - Fertility - post-implantation mortality (e.g. dead and/or resorbed implants per total number of implants)] Intraperitoneal. - Mouse LD50 : 260 mg/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.

Phenol :

Ecotoxicity:	Rainbow trout (Oncorhynchus mykiss) LC50 (96hr) : 5.02 mg/L Mrigal carp (Cirrhina mrigala) NOEC (60d) 0.077mg/L Water flea (Ceriodaphnia dubia) LC50 (48hr) 3.1mg/L, EC10 (16d) 0.46 mg/L Green algae (Selenastrum capricornutum) EC50 (96hr) : 61.1 mg/L Marine diatom (Skeletonema costatum) NOEC (120h) : 13 mg/L (OECD SIDS)
Biodegradation:	Phenol is readily biodegradable (OECD 301C: 85 % after 14 d).
Bioaccumulation:	Potential to bioaccumlate is low (BCF = 17.5).

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)

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)

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

Tobramycin Sulfate :

EINECS Number:	251-322-5
Canada DSL:	Listed

Phenol :

TSCA Inventory Status:	Listed
EINECS Number:	203-632-7
SARA:	EPCRA - 40 CFR Part 372 - (SARA Title III) Section 313 Listed Chemical.
Section 302 EHS:	EPCRA (SARA Title III) Section 302 (40 CFR Part 355) Extremely Hazardous Substances (EHS) Threshold Planning Quantity (TPQ) in pounds.: 500/10,000 Lbs.
Section 304 RQ:	EPCRA (SARA Title III) Section 304 Extremely Hazardous Substances (EHS) Reportable Quantities (RQ) in pounds.: 1,000 Lbs.

Canada DSL:	Listed
Canada IDL:	: 250 ppm

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)

Edetate Disodium :

TSCA Inventory Status:	Listed
EINECS Number:	205-358-3
Canada DSL:	Listed

SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

HMIS Health Hazard:	2
HMIS Fire Hazard:	0
HMIS Reactivity:	0
HMIS Personal Protection:	H

SDS Creation Date:	January 08, 2009
SDS Revision Date:	November 10, 2023
SDS Revision Notes:	Added HMIS Ratings for Health, Flammability, Reactivity, and Personal Protective Equipment (PPE).

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