# SAFETY DATA SHEET

## SECTION 1 : IDENTIFICATION

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| Product Name: | **Amikacin Sulfate Injection, USP** |
| Synonyms: | None. |
| Product Use/Restriction: | This material is the active pharmaceutical ingredient in a drug product; it is an aminoglycoside antibiotic. |
| Manufacturer Name: | Fresenius Kabi USA, LLC |
| Address: | Three Corporate Drive<br>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: | February 29, 2016 |
| SDS Revision Date: | February 12, 2024 |

## SECTION 2 : HAZARD(S) IDENTIFICATION

GHS Pictograms:

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| Signal Word: | WARNING. |
| GHS Class: | Reproductive toxicity. Category 1B.<br>Specific Target Organ Toxicity - STOT, Single Exposure SE. Category 3.<br>Reproductive toxicity. Effects on or via lactation. |
| Hazard Statements: | May damage fertility or the unborn child.<br>May cause drowsiness or dizziness.<br>May cause harm to breast-fed children. |
| Precautionary Statements: | Obtain special instructions before use.<br>Do not handle until all safety precautions have been read and understood.<br>Do not breathe dust/fume/gas/mist/vapours/spray.<br>Avoid breathing dust/fume/gas/mist/vapours/spray.<br>Avoid contact during pregnancy and while nursing.<br>Wash hands thoroughly after handling.<br>Do not eat, drink or smoke when using this product.<br>Use only outdoors or in a well-ventilated area.<br>Wear protective gloves/protective clothing/eye protection/face protection.<br>IF INHALED: Remove victim to fresh air and keep at rest in a position comfortable for breathing.<br>IF exposed or concerned: Get medical advice/attention.<br>Call a POISON CENTER or doctor/physician if you feel unwell.<br>Store in a well-ventilated place. Keep container tightly closed.<br>Store locked up.<br>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: | Neurotoxicity, manifested as vestibular and permanent bilateral auditory ototoxicity, can occur in patients with preexisting renal damage and in patients with normal renal function treated at higher doses and/or for periods longer than those recommended. The risk of aminoglycoside-induced ototoxicity is greater in patients with renal damage. High frequency deafness usually occurs first and can be detected only by audiometric testing. Vertigo may occur and may be evidence of vestibular injury. Other manifestations of neurotoxicity may include numbness, skin tingling, muscle twitching and convulsions. Patients developing cochlear damage may not have symptoms during therapy to warn them of developing eighth-nerve toxicity, and total or partial irreversible bilateral deafness may occur after the drug has been discontinued. Aminoglycoside-induced ototoxicity is usually irreversible (4).<br>Renal and eighth-nerve function should be closely monitored especially in patients with known or suspected renal impairment at the onset of therapy and also in those whose renal function is initially normal but who develop signs of renal dysfunction during therapy.<br>Patients treated with parenteral aminoglycosides should be under close clinical observation because of the potential ototoxicity and nephrotoxicity associated with their use.<br>In addition to those described above, other adverse reactions which have been reported on rare occasions are skin rash, drug fever, headache, paresthesia, tremor, nausea and vomiting, eosinophilia, arthralgia, anemia, hypotension, and hypomagnesemia. Macular infarction sometimes leading to permanent loss of vision has been reported following intravitreous administration (injection into the eye) of amikacin. |
| Aggravation of Pre-Existing Conditions: | A specific aminoglycoside preparation is contraindicated in patients with a history of hypersensitivity to that preparation or any ingredient in the formulation. Because there is evidence of cross-sensitivity among aminoglycosides, a history of toxic or hypersensitivity reaction to one aminoglycoside preparation may contraindicate the use of any other aminoglycoside |

## SECTION 3 : COMPOSITION/INFORMATION ON INGREDIENTS

| Chemical Name | CAS# | Ingredient Percent | EC Num. |
|---|---|---|---|
| Amikacin bis(sulphate) | 39831-55-5 | 5 - 25 mg/ml | |
| Sodium metabisulphite | 7681-57-4 | 0.13 - 0.66 % | |
| Trisodium citrate | 6132-04-3 | 0.5 - 2.5 % | |
| Sulfuric acid | 7664-93-9 | Quantity Sufficient to pH 3.5-5.5 | |
| Water for Injection | 7732-18-5 | Quantity Sufficient | |

## SECTION 4 : FIRST AID MEASURES

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| 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

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| Flash Point: | 101.5 °C Dry API |
| 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.<br>Use extinguishing measures that are appropriate to local circumstances and the surrounding environment. |
| Unsuitable Media: | Heavy water stream |
| Protective Equipment: | As in any fire, wear Self-Contained Breathing Apparatus (SCBA), MSHA/NIOSH (approved or equivalent) and full protective gear. |
| Unusual Fire Hazards: | When heated to decomposition it emits dangerous fumes |
| 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

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| 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

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| 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 20° to 25°C (68°to 77°F) [See USP Controlled Room Temperature]. |

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| 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

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| 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 metabisulphite :**

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| Guideline ACGIH: | TLV-TWA: 5 mg/m3 |

**Sulfuric acid :**

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| Guideline ACGIH: | TLV-TWA: 0.2 mg/m3 Total particulate/dust (T) |
| Guideline OSHA: | PEL-TWA: 1 mg/m3 |

## SECTION 9 : PHYSICAL and CHEMICAL PROPERTIES

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| Physical State: | Liquid solution. |
| Color: | Colorless. |
| Odor: | Odorless. |
| Boiling Point: | 343.7 °C at 760 mmHg API |
| Melting Point: | 220 – 230 °C API |
| Solubility: | Soluble. in water. |
| Vapor Density: | Not established. |
| Vapor Pressure: | Not established. |
| Percent Volatile: | Not established. |
| pH: | 3.5 - 5.0 |
| Flash Point: | 101.5 °C Dry API |
| Flash Point Method: | Not established. |
| Auto Ignition Temperature: | Not established. |

## SECTION 10 : STABILITY and REACTIVITY

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| Chemical Stability: | Stable under normal temperatures and pressures. |
| Hazardous Polymerization: | Not reported. |
| Conditions to Avoid: | Exposure to light or heat may cause decomposition. |
| Incompatible Materials: | Oxidizing agent. |
| Special Decomposition Products: | When heated to decomposition it emits dangerous fumes |

## SECTION 11 : TOXICOLOGICAL INFORMATION

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| Acute Toxicity: | All aminoglycosides have the potential to induce auditory, vestibular, and renal toxicity and neuromuscular blockade. They occur more frequently in patients with present or past history of renal impairment, of treatment with other ototoxic or nephrotoxic drugs, and in patients treated for longer periods and/or with higher doses than recommended. |

**Amikacin bis(sulphate) :**

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| Ingestion: | Oral - Rat LD50 - Lethal dose, 50 percent kill: >4 gm/kg [Details of toxic effects not reported other than lethal dose value] (RTECS) |
| Neurological Effects: | Toxic effects on the eighth cranial nerve can result in hearing loss, loss of balance, or both. Amikacin primarily affects auditory function. Cochlear damage, includes high frequency deafness and usually occurs before clinical hearing loss can be detected.<br>Acute muscular paralysis and apnea can occur following treatment with aminoglycoside drugs.<br>Elevation of serum creatinine, albuminuria, presence of red and white cells, casts, azotemia, and oliguria have been reported. Renal function changes are usually reversible when the drug is discontinued. As would be expected with any aminoglycoside, reports of toxic nephropathy and acute renal failure have been received during postmarketing surveillance. |
| Other Toxicological Information: | Intraperitoneal - Rat LD50 - Lethal dose, 50 percent kill: 3500 mg/kg [Details of toxic effects not reported other than lethal dose value]<br>Intraperitoneal - Mouse LD50 - Lethal dose, 50 percent kill: 2930 mg/kg [Details of toxic effects not reported other than lethal dose value]<br>Intravenous - Rat LD50 - Lethal dose, 50 percent kill: 234 mg/kg [Details of toxic effects not reported other than lethal dose value]<br>Intravenous - Mouse LD50 - Lethal dose, 50 percent kill: 181 mg/kg [Behavioral - Somnolence (general depressed activity) Behavioral - Ataxia Lungs, Thorax, or Respiration - Dyspnea]<br>Subcutaneous - Rat LD50 - Lethal dose, 50 percent kill: 3604 mg/kg [Details of toxic effects not reported other than lethal dose value]<br>Subcutaneous - Rat TDLo - Lowest published toxic dose: 12 gm/kg/30D (Intermittent) [Kidney/Ureter/Bladder - Changes in both tubules and glomeruli Kidney/Ureter/Bladder - Changes in bladder weight Nutritional and Gross Metabolic - Weight loss or decreased weight gain]<br>Subcutaneous - Rat (Female.8-14days(s) after conception) TDLo - Lowest published toxic dose: 175 mg/kg [Reproductive - Effects on Embryo or Fetus - Fetal death Reproductive - Effects on Newborn - growth statistics (e.g.,%, reduced weight gain)]<br>Subcutaneous - Rat (Female.8-14days(s) after conception) TDLo - Lowest published toxic dose: 2800 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - Musculoskeletal system Reproductive - Specific Developmental Abnormalities - Homeostasis]<br>Subcutaneous - Rat (Female.8-14days(s) after conception) TDLo - Lowest published toxic dose: 700 mg/kg [Reproductive - Fertility - Litter size (e.g., number fetuses per litter; measured before birth)]<br>Subcutaneous - Mouse LD50 - Lethal dose, 50 percent kill: 2470 mg/kg [Details of toxic effects not reported other than lethal dose value]<br>Subcutaneous - Mouse (Female.7-13days(s) after conception) TDLo - Lowest published toxic dose: 175 mg/kg [Reproductive - Effects on Embryo or Fetus - fetotoxicity (except death, e.g., stunted fetus) Reproductive - Specific Developmental Abnormalities - Musculoskeletal system]<br>Subcutaneous - Mouse (Female.7-13days(s) after conception) TDLo - Lowest published toxic dose: 700 mg/kg [Reproductive - Effects on Newborn - growth statistics (e.g.,%, reduced weight gain)] (RTECS) |

**Sodium metabisulphite :**

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| Eye: | Administration into the eye - Rabbit Standard Draize test: 100 mg/24H [Mild] (RTECS) |
| Skin: | Administration onto the skin - Rat LD50 - Lethal dose, 50 percent kill: >2 gm/kg [Details of toxic effects not reported other than lethal dose value] (RTECS) |
| Ingestion: | Oral - Rat LD50 - Lethal dose, 50 percent kill: 1131 mg/kg [Behavioral - Food intake (animal) Behavioral - Muscle weakness Skin and Appendages - Hair] (RTECS) |
| Other Toxicological Information: | Intravenous - Rat LD50 - Lethal dose, 50 percent kill: 115 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS) |

**Trisodium citrate :**

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| Other Toxicological Information: | Intraperitoneal - Rat LD50 - Lethal dose, 50 percent kill: 1548 mg/kg [Behavioral - Convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - Cyanosis Gastrointestinal - Changes in structure or function of salivary glands]<br>Intraperitoneal - Rat LD50 - Lethal dose, 50 percent kill: 1548 mg/kg [Behavioral - Convulsions or effect on seizure threshold Gastrointestinal - Changes in structure or function of salivary glands]<br>Intraperitoneal - Mouse LD50 - Lethal dose, 50 percent kill: 1364 mg/kg [Behavioral - Convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - Cyanosis Gastrointestinal - Changes in structure or function of salivary glands]<br>Intraperitoneal - Mouse LD50 - Lethal dose, 50 percent kill: 1364 mg/kg [Behavioral - Convulsions or effect on seizure threshold Gastrointestinal - Changes in structure or function of salivary glands]<br>Intravenous - Mouse LD50 - Lethal dose, 50 percent kill: 170 mg/kg [Behavioral - Convulsions or effect on seizure threshold Lungs, Thorax, or Respiration - Cyanosis Gastrointestinal - Changes in structure or function of salivary glands]<br>Intravenous - Mouse LD50 - Lethal dose, 50 percent kill: 170 mg/kg [Behavioral - Convulsions or effect on seizure threshold Gastrointestinal - Changes in structure or function of salivary glands] (RTECS) |

**Sulfuric acid :**

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|---|---|
| Eye: | Administration into the eye - Rabbit Standard Draize test: 250 ug [Severe]<br>Administration into the eye - Rabbit Rinsed with water: 5 mg/30S [Severe] (RTECS) |
| Inhalation: | Inhalation - Rat LC50 - Lethal concentration, 50 percent kill: 510 mg/m3/2H [Details of toxic effects not reported other than lethal dose value]<br>Inhalation - Rat LC50 - Lethal concentration, 50 percent kill: 510 mg/m3 [Details of toxic effects not reported other than lethal dose value] (RTECS) |
| Ingestion: | Oral - Rat LD50 - Lethal dose, 50 percent kill: 2140 mg/kg [Details of toxic effects not reported other than lethal dose value] (RTECS) |

## SECTION 12 : ECOLOGICAL INFORMATION

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| Ecotoxicity: | No ecotoxicity data was found for the product. |
| Environmental Stability: | No environmental information found for this product. |

## SECTION 13 : DISPOSAL CONSIDERATIONS

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| Waste Disposal: | Dispose of in accordance with Local, State, Federal and Provincial regulations. |

## SECTION 14 : TRANSPORT INFORMATION

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| DOT Shipping Name: | Not Regulated. |
| DOT UN Number: | Not Regulated. |

## SECTION 15 : REGULATORY INFORMATION

**Amikacin bis(sulphate) :**

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| California PROP 65: | Listed: developmental. |

**Sodium metabisulphite :**

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|---|---|
| TSCA Inventory Status: | Listed |
| Canada DSL: | Listed |

**Trisodium citrate :**

| | |
|---|---|
| TSCA Inventory Status: | Listed |
| Canada DSL: | Listed |

**Sulfuric acid :**

| | |
|---|---|
| TSCA Inventory Status: | Listed |
| Section 302 EHS: | EPCRA (SARA Title III) Section 302 (40 CFR Part 355) Extremely Hazardous Substances (EHS) Threshold Planning Quantity (TPQ) in pounds.: 1,000 |
| Section 313: | EPCRA - 40 CFR Part 372 - (SARA Title III) Section 313 Listed Chemical. |
| Canada DSL: | Listed |

## SECTION 16 : ADDITIONAL INFORMATION

HMIS Ratings:

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| HMIS Health Hazard: | 2* |
| HMIS Fire Hazard: | 0 |
| HMIS Reactivity: | 0 |
| HMIS Personal Protection: | C |

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| SDS Creation Date: | February 29, 2016 |
| SDS Revision Date: | February 12, 2024 |
| SDS Revision Notes: | Overall SDS review - no changes to formulation. Added HMIS ratings (for Health, Flammability, Reactivity, and Personal Protection Equipment [PPE]). |

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