


SAFETY DATA SHEETS

This SDS packet was issued with item:

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N/A

	Sagent Pharmaceuticals, Inc.		
	Document Type Safety Data Sheet (SDS)	Document Title Amikacin Sulfate Injection, USP	
	Document No. MSDS-0075	Version 2.0	Effective Date 29 Apr 2020

Section 1 - Identification

- (a) **Product Identifier:** Amikacin Sulfate Injection, USP
- (b) **NDC :** 25021-173
- Common/Trade Name:** N/A
- Chemical Name:** 0-3-amino-3-deoxy-a-D-glucopyranosyl-(1#4)-O-[6-amino-6-deoxy-a-D-glucopyranosyl-(1#6)]-N3-(4-amino-L-2-hydroxybutyryl)-2-deoxy-Lstreptamine sulfate (1:2)
- Chemical Family:** Aminoglycoside Antibiotic
- (c) **Product Use:** Short-term treatment of serious infections due to susceptible strains of Gram-negative bacteria, including Pseudomonas species, Escherichia coli, species of indole-positive and indole-negative.
- Product Type:** Regulated Prescription Drug
- Container Information:** Pre-filled glass vial
- (d) **Distributor:** Sagent Pharmaceuticals, Inc., 1901 N. Roselle Rd, Suite 450, Schaumburg, IL 60195, 847-908-1600
- (e) **Emergency Telephone:** 866-625-1618


Section 2 - Hazards Identification

- (a) **Classification:** U.S. OSHA Classification Possible Sensitizer
Target Organ Toxin
Possible Irritant.

- (b) **Signal Word,**
Hazard statement(s),
Symbol(s), and/or
Precautionary statement(s):
- | | |
|--------------------------|---|
| Hazard Statements | Aminoglycosides may cause potential ototoxicity and nephrotoxicity, as well as fetal harm, allergic-type reactions, and associate diarrhea. Please reference package insert for additional information. |
| Precautionary statements | P260 - Do not breathe dust/fume/gas/mist/vapors/spray. |

- (c) **Description of Hazards:** N/A

- (d) **Unknown Acute Toxicity:** N/A

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Section 3 – Composition / Information on Ingredients

500 mg/2 mL vial and 1g/ 4mL vial contains per each mL:

(a) Chemical Name	(b) Common Name / Synonym	% Composition or other measure	(c) CAS No.	(d) Impurities / Stabilizing Additives
Amikacin Sulfate	Amikacin Sulfate	21.12	39831-55-5	N/A
Sodium Citrate Dihydrate	Sodium Citrate Dihydrate	2.048	18996-35-5	N/A
Sodium Metabisulfite	Sodium Metabisulfite	.54	7681-57-4	N/A
Water for injection	Water	76.14	7732-18-5	N/A

Section 4 - First Aid Measures

Eye Exposure: Remove from source of exposure. Flush with copious amounts of water for at least 15 minutes. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

Skin Exposure: Remove contaminated shoes and clothing and cleanse affected area(s) thoroughly by washing with mild soap and water. If irritation or redness develops and persists, seek medical attention.


Ingestion: If swallowed, seek emergency medical attention. If victim is drowsy or unconscious and vomiting, place on the left side with the head down and DO NOT give anything by mouth. If not vomiting and professional advice is not available, DO NOT induce vomiting. If possible, do not leave victim unattended and observe closely for adequacy of breathing.

Injection: N/A

Inhalation: If respiratory symptoms develop, move victim away from source of exposure and into fresh air. If symptoms persist, seek medical attention. If victim is not breathing, clear airway and immediately begin artificial respiration. If breathing difficulties develop, oxygen should be administered by qualified personnel. Seek immediate medical attention.

Notes to Physician: See patient package insert in shipping carton for complete information.

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Section 5 –Fire-fighting Measures

- (a) **Extinguishing Media** Use extinguishing agent suitable for type of surrounding fire. Water spray, Carbon Dioxide, Halon, Foam, Dry Chemical, and any “ABC” Class extinguishers.
- (b) **Hazardous Combustion Products:** None anticipated for this aqueous product
- (c) **Special Protective Equipment / Precautions:** No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self-contained breathing apparatus.

Section 6 - Accidental Release Measures

Spill: Isolate area around spill. Put on suitable protective clothing and equipment as specified by site spill procedures. Absorb the liquid with suitable material and clean affected area with soap and water. Dispose of spill materials according to the applicable federal, state, or local regulations.

Release to Air: N/A

Release to Water: N/A

Section 7 - Handling and Storage

General Handling: No special handling required under conditions of normal product use.


Storage Conditions: Store at 20° to 25°C (68° to 77°F). For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

Section 8 - Exposure Controls / Personal Protection

(a) Exposure Limits

Compound	Issuer	Type	Exposure Limit
Amikacin	OSHA	PEL	Not available
	ACGIH	TLV	Not available
Sodium citrate dehydrate	OSHA	PEL	Not available

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	ACGIH	TLV	Not available
Sodium metabisulfite	OSHA ACGIH	PEL TLV	Not available 5 mg/m ³
Water for injection	OSHA ACGIH	PEL TLV	Not available Not available

(b) Engineering Controls

Ventilation: N/A

(c) Individual Protection Measures

Respiratory Protection:	Respiratory protection is normally not needed during intended product use. However, if the generation of aerosols is likely, and engineering controls are not considered adequate to control potential airborne exposures, the use of an approved air-purifying respirator with a HEPA cartridge (N95 or equivalent) is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. For uncontrolled release events, or if exposure levels are not known, provide respirators that offer a high protection factor such as a powered air purifying respirator or supplied air. A respiratory protection program that meets OSHA's 29 CFR 1910.134 and ANSI Z88.2 requirements must be followed whenever workplace conditions require respirator use. Personnel who wear respirators should be fit tested and approved for respirator use as required.
Eye Protection:	Eye protection is normally not required during intended product use. However, if eye contact is likely to occur, the use of chemical safety goggles (as a minimum) is recommended
Skin Protection:	If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.
Other Protective Equipment:	N/A
Additional Exposure Precautions:	N/A


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Section 9 - Physical and Chemical Properties

(a)	Appearance	Liquid; Colorless to light straw
(b)	Odor	N/A
(c)	Odor Threshold	N/A
(d)	pH	4.5 (3.5 to 5.5)
(e)	Melting Point:	N/A
(f)	Initial Boiling Point:	N/A
(g)	Flash Point	N/A
(h)	Evaporation Rate:	N/A
(i)	Flammability	N/A
(j)	Upper Lower Flammability or Explosion Limits	N/A
(k)	Vapor Pressure:	N/A
(l)	Vapor Density:	N/A
(m)	Relative Density	N/A
(n)	Solubility(ies)	N/A
(o)	Partition Coefficient: n-octanol/water	N/A
(p)	Auto-ignition Temperature	N/A
(q)	Decomposition Temperature	N/A
(r)	Viscosity	N/A

Section 10 - Stability and Reactivity

(a)	Reactivity	Not determined
(b)	Chemical Stability	Stable under standard use and storage conditions.
(c)	Possibility of Hazardous Reactions	Not determined
(d)	Conditions to Avoid	Not determined
(e)	Incompatible Materials	Not determined

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Section 11 - Toxicological Information

(a)	Likely Routes of Exposure	Injection, Ingestion, skin, eye.
(b)	Symptoms related to the physical, chemical and toxicological characteristics	<p>Injection: Local redness, swelling and/or pain; Flu-like symptoms, dizziness, loss of balance and hearing loss.</p> <p>Skin: redness, itching burning, skin damage</p> <p>Eyes: stinging, watering, redness, swelling</p> <p>See package insert for more information.</p>
(c)	Delayed and immediate effects and also chronic effects from short and long term exposure	<p>Primary health effects include irritation of eyes and skin, and local swelling after injection (See above symptoms).</p> <p>Chronic overexposure: may cause damage to hearing, kidneys and nervous system.</p> <p>See package insert for more information.</p>

(d) Acute Toxicity

Component	Type	Route	Species	Dosage
Amikacin Sulfate	LD ₅₀	Oral	Mouse Rat Rabbit	>10,679 mg/Kg >4000 mg/Kg >3000 mg/Kg
Amikacin Sulfate	LD ₅₀	Intravenous	Mouse Rat Rabbit Dog	181 mg/Kg 234 mg/Kg 248 mg/Kg 383 mg/Kg
Sodium Citrate Dihydrate	N/A	N/A	N/A	N/A

(e) Hazardous Chemical Listings

NTP: No


IARC: No

OSHA: No

NIOSH Listed: No

Section 12 - Ecological Information

(a)	Ecotoxicity	N/A
(b)	Persistence and degradability	Not determined for product.
(c)	Bioaccumulative potential	Not determined for product.
(d)	Mobility in soil	Not determined for product.
(e)	Other Adverse Effects	Not determined for product.
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Section 13 - Disposal Considerations

Description of waste residues and information on their safe handling and methods of disposal, including the disposal of any contaminated packaging.

Section 14 - Transport Information

DOT: Not regulated
IMDG: Not regulated
ICAO/ IATA: Not regulated

Section 15 - Regulatory Information

Below is selected regulatory information chosen primarily for possible Sagent usage. This section is not a complete analysis or reference to all applicable regulatory information. Please consider all applicable laws and regulations for your country/state.

U.S. Regulations:

TSCA: No
CERCLA: Not on this list
SARA 302: Not on this list
SARA 313: Not on this list


Section 16 - Other Information

As of the date of issuance, we are providing available information relevant to the handling of this material in the workplace. All information contained herein is offered with the good faith belief that it is accurate. THIS SAFETY DATA SHEET SHALL NOT BE DEEMED TO CREATE ANY WARRANTY OF ANY KIND (INCLUDING WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE). In the event of an adverse incident associated with this material, this safety data sheet is not intended to be a substitute for consultation with appropriately trained personnel. Nor is this safety data sheet intended to be a substitute for product literature which may accompany the finished product.

For additional information contact:
Sagent Pharmaceuticals, Inc.
1901 N. Roselle Rd, Suite 450
Schaumburg, IL 60195
847-908-1600


Glossary: This glossary contains definitions of general terms used in SDSs. Not all of these Glossary Terms will apply to this SDS.

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ACGIH	American Conference of Governmental Industrial Hygienists
AICS	Australian Inventory of Chemical Substances
AIHA	American Industrial Hygiene Association
ANSI	American National Standards Institute
CAS Number	Chemical Abstract Service Registry Number
CERCLA	Comprehensive Environmental Response Compensation and Liability Act (of 1980)
CHAN	Chemical Hazard Alert Notice
CHEMTREC	Chemical Transportation Emergency Center
DOT	Department of Transportation
DSL	Domestic Substances List
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	European List of Notified Chemical Substances
EPA	Environmental Protection Agency
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HEPA	High Efficiency Particulate Air (Filter)
HMIS	Hazardous Materials Identification System
IARC	International Agency for Research on Cancer
ICAO/IATA	International Civil Aviation Organization/International Air Transport Association
IMO	International Maritime Organization
KOW	Octanol/Water Partition Coefficient
LEL	Lower Explosive Limit
MSDS	Material Safety Data Sheet
MSHA	Mine Safety and Health Administration
NA	Not Applicable, except in Section 14 where NA = North America
NE	Not Established
NADA	New Animal Drug Application
NAIF	No Applicable Information Found
NCI	National Cancer Institute
NDSL	Non-Domestic Substances List
NFPA	National Fire Protection Association
NIOSH	National Institute for Occupational Safety and Health
NPDES	National Pollutant Discharge Elimination System
NOS	Not Otherwise Specified
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration
OEL	Occupational Exposure Limit
PEL	Permissible Exposure Limit (OSHA)
RCRA	Resource Conservation and Recovery Act
RQ	Reportable Quantity

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RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
SDS	Safety Data Sheet
STEL	Short Term Exposure Limit
TLV	Threshold Limit Value (ACGIH)
TPQ	Threshold Planning Quantity
TSCA	Toxic Substances Control Act
TWA	Time Weighted Average/8 Hours Unless Otherwise Noted
UEL	Upper Explosive Limit
UN	United Nations
USP	United States Pharmacopeia
WEEL	Workplace Environmental Exposure Level (AIHA)
WHMIS	Workplace Hazardous Materials Information System