

MATERIAL SAFETY DATA SHEET

Product Name: Gentamicin Sulfate in 0.9% Sodium Chloride Injection

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address Hospira Inc.
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 Lake Forest, Illinois USA
 60045

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Hospira, Inc., Non-Emergency 224-212-2000

Product Name Gentamicin Sulfate in 0.9% Sodium Chloride Injection

Synonyms Gentamicin Sulfate, USP; 0-3-Deoxy-4-C-methyl-3(methylamino)-β-L-arabinopyranosyl-(1-> 6 -0-[2,6-diamino-2,3,4,6-tetradeoxy-α-D-erythrohexopyranosyl-(1->4)]-2-deoxy-D-streptamine.

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Gentamicin Sulfate

Chemical Formula NA

Preparation Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% include sodium chloride. Sulfuric acid and/or sodium hydroxide are added for pH adjustment.

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Gentamicin Sulfate	1	1405-41-0	LY2625000

3. HAZARD INFORMATION

Carcinogen List

Substance	IARC	NTP	OSHA
Gentamicin Sulfate	Not Listed	Not Listed	Not Listed

Emergency Overview Gentamicin Sulfate in 0.9% Sodium Chloride Injection is a solution containing gentamicin sulfate, a complex aminoglycoside antibiotic substance with three components, sulfates of gentamicin C1, gentamicin C2 and gentamicin C1A. Clinically, gentamicin sulfate is used to treat severe systemic infections due to sensitive Gram-negative and other organisms. In the workplace, this material should be considered potentially irritating to the eyes and respiratory system, a potential sensitizer, and a potential reproductive hazard. Based on clinical use, possible target organs include the kidneys, hearing, nervous system, gastrointestinal system, eyes and fetus.

Occupational Exposure Potential Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.

Signs and Symptoms None known from work place exposure. In clinical use, adverse effects may include nausea,

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vomiting, diarrhea, headache, depression, dizziness, , impaired balance and eye irritation, skin rashes, respiratory depression, possible kidney injury and hearing loss. Nephrotoxicity manifested by an elevated BUN or serum creatinine level or a decrease in the creatinine clearance has been reported with gentamicin. Gentamicin has produced vestibular and auditory toxicity in man and in experimental animals. Neurotoxicity manifested by ototoxicity, both vestibular and auditory, can occur in patients treated with gentamicin sulfate. Gentamicin-induced ototoxicity is usually irreversible. Allergic reactions have also been reported.

Medical Conditions Aggravated by Exposure Pre-existing hypersensitivity to gentamicin sulfate or related products; pre-existing ocular, renal, auditory or gastrointestinal ailments; pregnancy.

4. FIRST AID MEASURES

Eye contact	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Skin contact	Remove from source of exposure. Flush with copious amounts of water. If irritation persists or signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Inhalation	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
Ingestion	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

5. FIRE FIGHTING MEASURES

Flammability	None anticipated for this aqueous product.
Fire & Explosion Hazard	None anticipated for this aqueous product.
Extinguishing media	As with any fire, use extinguishing media appropriate for primary cause of fire.
Special Fire Fighting Procedures	No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

6. ACCIDENTAL RELEASE MEASURES

Spill Cleanup and Disposal	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.
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7. HANDLING AND STORAGE

Handling	No special handling required for hazard control.
Storage	No special storage required for hazard control. For product protection, follow storage recommendations noted on the product case label, the primary container label, or the product insert.

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Special Precautions No special precautions required for hazard control. Employees with known allergies to gentamicin sulfate or related antibiotics should consult a health and/or safety professional prior to handling open containers of this material.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

Component	Type	Exposure limits			Note
		mg/m ³	ppm	µg/m ³	
Gentamicin Sulfate	Not Applicable	N/A	N/A	N/A	None Established

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. Since protection provided by air purifying respirators is limited, a powered air purifying respirator or supplied air should be considered during an uncontrolled release event, if exposure levels are not known, or during events where air-purifying respirators may not provide adequate protection. 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.

Skin protection If skin contact with the product formulation is likely, the use of latex or nitrile gloves is recommended.

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.

Engineering Controls Engineering controls are normally not needed during the normal use of this product.

9. PHYSICAL/CHEMICAL PROPERTIES

Appearance/Physical State	Liquid
Color	Clear, colorless
Odor	NA
Odor Threshold:	NA
pH:	3.8 (3.0 to 5.5)
Melting point/Freezing point:	NA
Initial Boiling Point/Boiling Point Range:	NA
Evaporation Rate:	NA
Flammability (solid, gas):	NA
Upper/Lower Flammability or Explosive Limits:	NA
Vapor Pressure:	NA
Vapor Density:	NA
Specific Gravity:	NA
Solubility:	Gentamicin Sulfate is soluble in water, moderately soluble in methanol, ethanol, acetone and practically insoluble in benzene.
Partition coefficient: n-octanol/water:	NA
Auto-ignition temperature:	NA

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Decomposition temperature: NA

10. STABILITY AND REACTIVITY

Reactivity	Not determined.
Chemical Stability	Stable under standard use and storage conditions.
Hazardous Reactions	Not determined.
Conditions to avoid	Not determined.
Incompatibilities	Not determined.
Hazardous decomposition products	Not determined. During thermal decomposition, it may be possible to generate irritating vapors and/or toxic fumes of carbon oxides (COx), nitrogen oxides (NOx), and sulfur oxides (SOx).
Hazardous Polymerization	Not anticipated to occur with this product.

11. TOXICOLOGICAL INFORMATION

Acute Toxicity

Not determined for the product formulation. Information for the ingredients is as follows:

Ingredient(s)	Percent	Test Type	Route of Administration	Value	Units	Species
Gentamicin Sulfate	100	LD50	Oral	> 5000	mg/kg	Rat
				> 11,269	mg/kg	Mouse
				> 9050	mg/kg	Mouse
Gentamicin Sulfate	100	LD50	Intravenous	96	mg/kg	Rat
				47	mg/kg	Mouse
				75	mg/kg	Mouse
Gentamicin Sulfate	100	LD50	Intraperitoneal	630	mg/kg	Rat
				245	mg/kg	Mouse
				430	mg/kg	Mouse

Aspiration Hazard None anticipated from normal handling of this product.

Dermal Irritation/Corrosion None anticipated from normal handling of this product.

Ocular Irritation/Corrosion None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation. Gentamicin sulfate produced significant conjunctival irritation in an irritation study in animals.

Dermal or Respiratory Sensitization None anticipated from normal handling of this product. Allergic reactions have been reported during the clinical use of this product in patients.

Reproductive Effects Animal reproduction studies conducted on rats and rabbits did not reveal evidence of impaired fertility or harm to the fetus due to gentamicin sulfate. Aminoglycoside antibiotics cross the placenta, and there have been several reports of total irreversible bilateral congenital deafness in children whose mothers received streptomycin or tobramycin during pregnancy. Also, aminoglycosides may be nephrotoxic in the human fetus. FDA Pregnancy Category D.

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Mutagenicity The mutagenic potential of gentamicin sulfate has not been evaluated.

Carcinogenicity The carcinogenic potential of gentamicin sulfate has not been evaluated.

Target Organ Effects Gentamicin has produced vestibular and auditory toxicity in patients and experimental animals. Based on clinical use, possible target organs include the kidneys, hearing, nervous system, gastrointestinal system, eyes and fetus.

12. ECOLOGICAL INFORMATION

Aquatic Toxicity Not determined for product

Persistence/Biodegradability Not determined for product

Bioaccumulation Not determined for product

Mobility in Soil Not determined for product

13. DISPOSAL CONSIDERATIONS

Waste Disposal All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.

Container Handling and Disposal Dispose of container and unused contents in accordance with federal, state and local regulations.

14. TRANSPORTATION INFORMATION

ADR/ADG/ DOT STATUS: Not regulated

IMDG STATUS: Not regulated

ICAO/IATA STATUS: Not regulated

Transport Comments: None

15. REGULATORY INFORMATION

USA Regulations

Substance	TSCA Status	CERCLA Status	SARA 302 Status	SARA 313 Status	PROP 65 Status
Gentamicin Sulfate	Not Listed	Not Listed	Not Listed	Not Listed	Listed

RCRA Status Not Listed

U.S. OSHA Classification Possible Irritant
Possible Reproductive Toxin
Target Organ Toxin

GHS Classification *In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

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Hazard Class	Not Applicable
Hazard Category	Not Applicable
Signal Word	Not Applicable
Symbol	Not Applicable
Prevention	P260 - Do not breathe dust/fume/gas/mist/vapors/spray.
Hazard Statement	Not Applicable
Response:	IF IN EYES: Rinse cautiously with water for several minutes. Remove contact lenses, if present and easy to do. Continue rinsing. If eye irritation persists, get medical attention. Wash hands after handling. Get medical attention if you feel unwell.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Gentamicin Sulfate

Classification(s):	Not Applicable
Symbol:	Not Applicable
Indication of Danger:	Not Applicable
Risk Phrases:	Not Applicable
Safety Phrases:	S23 - Do not breathe vapor. S24/25 - Avoid contact with skin and eyes. S37/39 - Wear suitable gloves and eye/face protection.

16. OTHER INFORMATION:

Notes:

ACGIH TLV	American Conference of Governmental Industrial Hygienists – Threshold Limit Value
CAS	Chemical Abstracts Service Number
CERCLA	US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act
DOT	US Department of Transportation Regulations
EEL	Employee Exposure Limit
IATA	International Air Transport Association
LD50	Dosage producing 50% mortality
NA	Not applicable/Not available
NE	Not established
NIOSH	National Institute for Occupational Safety and Health
OSHA PEL	US Occupational Safety and Health Administration – Permissible Exposure Limit
Prop 65	California Proposition 65
RCRA	US EPA, Resource Conservation and Recovery Act
RTECS	Registry of Toxic Effects of Chemical Substances
SARA	Superfund Amendments and Reauthorization Act
STEL	15-minute Short Term Exposure Limit
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

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MSDS Coordinator: Hospira GEHS

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