SAFETY DATA SHEET

Product Name: Gentamicin Sulfate Injection

1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

Manufacturer Name And Address	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
Emergency Telephone	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
Hospira, Inc., Non-Emergency	224 212-2000
Product Name	Gentamicin Sulfate Injection
Synonyms	Gentamicin Sulfate, USP; 0-3-Deoxy-4-C-methyl-3(methylamino)-ß-L-arabinopyranosyl-(1-> 6 -0-[2,6-diamino-2,3,4,6-tetradeoxy-α-D-erythro-hexopyranosyl-(l->4)]-2-deoxy-D-streptamine.

2. HAZARD(S) IDENTIFICATION

Emergency Overview

Gentamicin Sulfate 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 occupational reproductive hazard. Based on clinical use, possible target organs include the kidneys, hearing, nervous system, and gastrointestinal system.

U.S. OSHA GHS Classification

Physical Hazards	**Hazard Class**	**Hazard Category**
	Not Classified	Not Classified

Health Hazards	**Hazard Class**	**Hazard Category**
	Sensitization – Respiratory	1
	Sensitization – Skin	1
	Toxic to Reproduction	2
	STOT – RE	2

Label Element(s)

Pictogram

Signal Word

Danger

Hazard Statement(s)

May cause allergy or asthma symptoms or breathing difficulties if inhaled
May cause an allergic skin reaction
Suspected of damaging fertility or the unborn child
May cause damage to organs through prolonged or repeated exposure

2. HAZARD(S) IDENTIFICATION: continued

Precautionary Statement(s)

Prevention

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wear protective gloves/protective clothing/eye protection/face protection
Avoid breathing vapors/spray
In case of inadequate ventilation, wear respiratory protection
Contaminated work clothing must not be allowed out of the workplace
Wash hands thoroughly after handling

Response

If exposed or concerned: Get medical advice/attention.

IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a doctor.

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.

IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Gentamicin Sulfate
Chemical Formula NA

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Gentamicin Sulfate	4	1405-41-0	LY2625000

Non-hazardous ingredients include Water for Injection. Hazardous ingredients which may be present at less than 1% include sodium metabisulfite, edetate disodium anhydrous, methylparaben, and propylparaben. Product may contain sulfuric acid and/or sodium hydroxide for pH adjustment.

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 such as carbon dioxide, dry chemical extinguishing powder or foam.

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 control 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.

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.

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

	Exposure Limits			
Component	**OSHA-PEL**	**ACGIH-TLV**	**AIHA WEEL**	**Hospira EEL**
Gentamicin Sulfate	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established

Notes: OSHA PEL: US Occupational Safety and Health Administration – Permissible Exposure Limit
ACGIH TLV: American Conference of Governmental Industrial Hygienists – Threshold Limit Value.
AIHA WEEL: Workplace Environmental Exposure Level
EEL: Employee Exposure Limit.
TWA: 8-hour Time Weighted Average.

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	A sterile, nonpyrogenic solution
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
Flash Point	NA
Evaporation Rate	NA
Flammability (solid, gas)	NA
Upper/Lower Flammability or Explosive Limits	NA
Vapor Pressure	NA
Vapor Density (Air =1)	NA
Relative Density	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
Decomposition Temperature	NA
Viscosity	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 active ingredient is as follows:

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

LD 50: Dosage that produces 50% mortality.

11. TOXICOLOGICAL INFORMATION: continued

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 anticipated from normal handling of this product. In clinical use, adverse effects may include nausea, 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.
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 conjuctival 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. This product contains sodium metabisulfite which may cause allergic-type reactions in susceptible people.
Reproductive Effects	None anticipated from normal handling of this product. 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.
Mutagenicity	The mutagenic potential of gentamicin sulfate has not been evaluated.
Carcinogenicity	The carcinogenic potential of gentamicin sulfate has not been evaluated.
Carcinogen Lists	**IARC:** Not listed **NTP:** Not listed **OSHA:** Not listed
Specific Target Organ Toxicity – Single Exposure	NA
Specific Target Organ Toxicity – Repeat Exposure	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, and gastrointestinal system.

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.

Notes:

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
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
ICAO/IATA STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA
IMDG STATUS	Not regulated
Proper Shipping Name	NA
Hazard Class	NA
UN Number	NA
Packing Group	NA
Reportable Quantity	NA

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

US TSCA Status	Exempt
US CERCLA Status	Not listed
US SARA 302 Status	Not listed
US SARA 313 Status	Not listed
US RCRA Status	Not listed
US PROP 65 (Calif.)	This product contains an aminoglycoside, a chemical known to the State of California to cause developmental reproductive toxicity.

Notes: TSCA, Toxic Substance Control Act; CERCLA, US EPA law, Comprehensive Environmental Response, Compensation, and Liability Act; SARA, Superfund Amendments and Reauthorization Act; RCRA, US EPA, Resource Conservation and Recovery Act; Prop 65, California Proposition 65

15. REGULATORY INFORMATION: continued

GHS/CLP 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.

Hazard Class	Hazard Category	Pictogram	Signal Word	Hazard Statement
NA	NA	NA	NA	NA

Prevention

Obtain special instructions before use
Do not handle until all safety precautions have been read and understood
Wear protective gloves/protective clothing/eye protection/face protection
Avoid breathing vapors/spray
In case of inadequate ventilation, wear respiratory protection
Contaminated work clothing must not be allowed out of the workplace
Wash hands thoroughly after handling

Response

If exposed or concerned: Get medical advice/attention.

IF INHALED: If breathing is difficult, remove person to fresh air and keep comfortable for breathing. If experiencing respiratory symptoms: Call a doctor.

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.

IF ON SKIN: Wash with plenty of water. If skin irritation or rash occurs: Get medical advice/attention. Wash contaminated clothing before reuse.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive.

Classification(s) NA
Symbol NA
Indication of Danger NA
Risk Phrases NA
Safety Phrases
S23: Do not breathe vapor/spray
S24: Avoid contact with the skin
S25: Avoid contact with eyes
S37/39 Wear suitable gloves and eye/face protection
R42/43 - May cause sensitization by inhalation and skin contact

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
LD_{50}	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
STOT - SE	Specific Target Organ Toxicity – Single Exposure
STOT - RE	Specific Target Organ Toxicity – Repeated Exposure
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS
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