SAFETY DATA SHEET

Product Name: Pentamidine Isethionate for Injection, BP

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	Pentamidine Isethionate for Injection, BP
Synonyms	4,4'-(pentamethylenedioxy)-dibenzamidine isetionate

2. HAZARD(S) IDENTIFICATION

Emergency Overview

Pentamidine Isethionate for Injection, BP is a lyophilized powder that contains pentamidine isethionate, an anti-parasitic aromatic diamidine. Clinically, it is indicated for the treatment of pneumonia due to *Pneumocystis carinii*. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract. Based on clinical use, possible target organs include the cardiovascular system, blood, kidneys, liver, and respiratory system.

U.S. OSHA GHS Classification

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

Health Hazards	**Hazard Class**	**Hazard Category**
	Not Classified	Not Classified

Label Element(s)

Pictogram

Signal Word

Hazard Statement(s)

Precautionary Statement(s)

Prevention	Do not breathe vapor or spray Wash hands thoroughly after handling
Response	Get medical attention if you feel unwell. 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.

3. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Pentamidine Isethionate
Chemical Formula $C_{23}H_{36}N_4O_{10}S_2$

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Pentamidine Isethionate	100	140-64-7	CV6500000

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 product. However, many organic powders will combust at high temperatures.

Fire & Explosion Hazard None anticipated for this product. Avoid the creation of dusty environments.

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. Collect powder using techniques that minimize the creation of airborne dusts. If the spill occurs after reconstitution, absorb spill using an inert absorbent material. 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 under conditions of normal product use.

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.

8. EXPOSURE CONTROLS/PERSONAL PROTECTION

Exposure Guidelines

	Exposure Limits			
Component	**OSHA-PEL**	**ACGIH-TLV**	**AIHA WEEL**	**Hospira EEL**
Pentamidine Isethionate	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 dusts or 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 dust or 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.

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	Pentamidine Isetionate for Injection, BP is a sterile lyophilized powder for injection. It contains no preservative.
Odor	NA
Odor Threshold	NA
pH	4.5 to 7.5 after reconstitution
Melting point/Freezing Point	180^{o}C
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	Soluble in water and glycerin. Slightly soluble in alcohol. Insoluble in ether, acetone and chloroform.
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
Pentamidine Isethionate	100	LD50	Intravenous	15.1 28	mg/kg mg/kg	Mouse Mouse

LD 50: Dosage that produces 50% mortality.

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, fatalities due to severe hypotension, hypoglycemia and cardiac arrhythmias have been reported in patients treated with pentamidine isetionate. Profound and severe hypotension can occur after a single dose. More common adverse effects may include fainting, breathlessness, headache, nausea, vomiting, fever, dizziness, renal injury, cardiac irregularity, and hematologic changes. Following aerosol use, bronchospasm, rashes and air way irritation have been the predominant adverse effects found. Cough has occurred in up to 38% of patients following oral inhalation via nebulization. Bronchospasm has occurred in up to 15% of patients and may be associated with local histamine release in the bronchial mucosa (may be more likely in asthmatics). Ventricular tachycardia and ECG abnormalities may develop in patients receiving pentamidine isetionate. Leukopenia and thrombocytopenia, which can be severe, may occur occasionally in patients receiving pentamidine isetionate. Anemia occurs rarely. In a few cases, pentamidine therapy has been associated with neutropenia. Phlebitis can occur after intravenous injection.

Aspiration Hazard None anticipated from normal handling of this product. Inadvertent inhalation of product aerosol may produce respiratory irritation with coughing.

Dermal Irritation/Corrosion None anticipated from normal handling of this product. Pentamidine isethionate was not irritating to the skin in a skin irritation test in rabbits.

Ocular Irritation/Corrosion None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce severe irritation. In animals, pentamidine isethionate is a severe eye irritant; it produced maximal corneal opacity in an eye irritation test.

Dermal or Respiratory Sensitization None anticipated from normal handling of this product. However, in clinical use, bronchospasm, irritation and coughing have been reported following the inhalation of nebulized product.

11. TOXICOLOGICAL INFORMATION: continued

Reproductive Effects	None anticipated from normal handling of this product. Pentamidine isethionate was given to pregnant rats at dosages of 0, 4, and 20 mg/kg/day on days 6-11, 6-8, or 9-11 of gestation. A significant increase in embryotoxicity was noted following administration of 4 mg/kg/day during days 6-11 of gestation. Pentamidine Isetionate was assessed for feto-toxicity and teratogenic activity in mated female New Zealand white rabbits at dosage levels of 1, 2, 3 and 8 mg/kg intravenously once daily from gestation days 5 through 12. Maternal toxicity (severe central nervous system, somatomotor, respiratory and cardiovascular reactions) was evident at 8 mg/kg. A dose-related decrease in body weight and food consumption was also noted in the dams. Litter data parameters (viable fetuses, litter weight and fetal weight, sex ratio) remained largely unaffected by treatment except for a mild feto-toxic effect in all dosage groups as indicated by increased post-implantation loss and increased incidence of minor fetal skeletal anomalies which may have been linked to maternal toxicity.
Mutagenicity	Pentamidine isethionate was negative in the Ames Assay, with and without metabolic activation.
Carcinogenicity	The carcinogenic potential of pentamidine isethionate 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	Based on clinical use, possible target organs include the cardiovascular system, blood, kidneys, liver, and respiratory 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.)	Not listed

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

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
Do not breathe vapor or spray
Wash hands thoroughly after handling

Response
Get medical attention if you feel unwell.

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.

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.

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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Disclaimer:

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