



## SAFETY DATA SHEET

**Product Name: Pancuronium Bromide Injection**

### 1. CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

<b>Manufacturer Name And Address</b>	Hospira, Inc. 275 North Field Drive Lake Forest, Illinois 60045 USA
<b>Emergency Telephone</b>	CHEMTREC: North America: 800-424-9300; International 1-703-527-3887; Australia - 61-290372994; UK - 44-870-8200418
<b>Hospira, Inc., Non-Emergency</b>	224 212-2000
<b>Product Name</b>	Pancuronium Bromide Injection
<b>Synonyms</b>	2 $\beta$ , 16 $\beta$ - dipiperidino-5 $\alpha$ -androstane-3 $\alpha$ , 17- $\beta$ diol diacetate dimethobromide

### 2. HAZARD(S) IDENTIFICATION

<b>Emergency Overview</b>	Pancuronium Bromide Injection is a solution containing pancuronium bromide, a neuromuscular blocking agent used to aid general anesthesia and intratracheal intubation. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract, and a potent drug. Based on clinical use, possible target organs include the central nervous system, respiratory system, muscular system and cardiovascular system.
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#### U.S. OSHA GHS Classification

<b>Physical Hazards</b>	<b>Hazard Class</b>	<b>Hazard Category</b>
	Not Classified	Not Classified

<b>Health Hazards</b>	<b>Hazard Class</b>	<b>Hazard Category</b>
	Not Classified	Not Classified

<b>Label Element(s)</b>	
<b>Pictogram</b>	NA
<b>Signal Word</b>	NA
<b>Hazard Statement(s)</b>	NA

#### **Precautionary Statement(s)**

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

<b>Active Ingredient Name</b>	Pancuronium Bromide	Benzyl Alcohol
<b>Chemical Formula</b>	C <sub>35</sub> H <sub>60</sub> Br <sub>2</sub> N <sub>2</sub> O <sub>4</sub>	C <sub>7</sub> H <sub>8</sub> O

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Pancuronium Bromide	0.1	15500-66-0	TN4930000
Benzyl Alcohol	1	100-51-6	DN3150000

Non-hazardous ingredients include Water for Injection. Hazardous ingredients present at less than 1% may include sodium acetate and sodium chloride. Acetic acid and/or sodium hydroxide may be used to adjust the pH.

**4. FIRST AID MEASURES**

<b>Eye Contact</b>	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.
<b>Skin Contact</b>	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.
<b>Inhalation</b>	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.
<b>Ingestion</b>	Remove from source of exposure. If signs of toxicity occur, seek medical attention. Provide symptomatic/supportive care as necessary.

**5. FIRE FIGHTING MEASURES**

<b>Flammability</b>	None anticipated for this aqueous product. However, when heated, this product may release combustible vapors.
<b>Fire &amp; Explosion Hazard</b>	None anticipated for this aqueous product.
<b>Extinguishing Media</b>	As with any fire, use extinguishing media appropriate for primary cause of fire such as carbon dioxide, dry chemical extinguishing powder or foam.
<b>Special Fire Fighting Procedures</b>	No special provisions required beyond normal firefighting equipment such as flame and chemical resistant clothing and self contained breathing apparatus.

**6. ACCIDENTAL RELEASE MEASURES**

<b>Spill Cleanup and Disposal</b>	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.
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**7. HANDLING AND STORAGE**

<b>Handling</b>	No special handling required for hazard control under conditions of normal product use.
<b>Storage</b>	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.
<b>Special Precautions</b>	No special precautions required for hazard control.

## 8. EXPOSURE CONTROLS/PERSONAL PROTECTION

### Exposure Guidelines

Component	Exposure Limits			
	OSHA-PEL	ACGIH-TLV	AIHA WEEL	Hospira EEL
Pancuronium Bromide	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established	8-hr TWA: Not Established
Benzyl Alcohol	8 hr TWA: Not Established	8 hr TWA: Not Established	8-hr TWA: 10 ppm	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 or vapors 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.

### 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

<b>Appearance/Physical State</b>	A sterile, isotonic, nonpyrogenic solution for injection
<b>Odor</b>	NA
<b>Odor Threshold</b>	NA
<b>pH</b>	4.0 (3.8 to 4.2)
<b>Melting point/Freezing Point</b>	NA
<b>Initial Boiling Point/Boiling Point Range</b>	NA
<b>Flash Point</b>	NA
<b>Evaporation Rate</b>	NA
<b>Flammability (solid, gas)</b>	NA
<b>Upper/Lower Flammability or Explosive Limits</b>	NA
<b>Vapor Pressure</b>	NA
<b>Vapor Density (Air =1)</b>	NA
<b>Relative Density</b>	NA
<b>Solubility</b>	NA
<b>Partition Coefficient: n-octanol/water</b>	NA
<b>Auto-ignition Temperature</b>	NA
<b>Decomposition Temperature</b>	NA
<b>Viscosity</b>	NA

## 10. STABILITY AND REACTIVITY

<b>Reactivity</b>	Not determined.
<b>Chemical Stability</b>	Stable under standard use and storage conditions.
<b>Hazardous Reactions</b>	Not determined
<b>Conditions to Avoid</b>	Not determined
<b>Incompatibilities</b>	Not determined
<b>Hazardous Decomposition Products</b>	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 hydrogen bromide.
<b>Hazardous Polymerization</b>	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
Pancuronium Bromide	100	LD50	Oral	202 21.2	mg/kg mg/kg	Rat Mouse
Pancuronium Bromide	100	LD50	Intravenous	153 13 16	mcg/kg mcg/kg mcg/kg	Rat Mouse Rabbit
Benzyl Alcohol	100	LD50	Oral	1040-2500	mg/kg	Rat, Mouse, Rabbit, Guinea Pig
Benzyl Alcohol	100	LD50	Dermal	2000	mg/kg	Rabbit

LD 50: Dosage that produces 50% mortality.

<b>Occupational Exposure Potential</b>	Information on the absorption of this product via inhalation or skin contact is not available. Avoid liquid aerosol generation and skin contact.
<b>Signs and Symptoms</b>	None anticipated from normal handling of this product. In clinical use, pancuronium may cause a moderate rise in heart rate, mean arterial pressure and cardiac output. Other reactions may include excessive salivation, excessive sweating and occasionally transient rashes and wheezing. Other reactions generally relate to an extension of the drug's pharmacological action beyond the time period needed; these reactions may vary from skeletal muscle weakness to profound and prolonged skeletal muscle paralysis resulting in respiratory distress or apnea.
<b>Aspiration Hazard</b>	None anticipated from normal handling of this product.
<b>Dermal Irritation/ Corrosion</b>	None anticipated from normal handling of this product.
<b>Ocular Irritation/ Corrosion</b>	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce mild irritation with redness and tearing.
<b>Dermal or Respiratory Sensitization</b>	None anticipated from normal handling of this product. In clinical use, rare hypersensitivity reactions such as bronchospasm, flushing, redness, hypotension, tachycardia and other reactions possibly mediated by histamine release have been reported.

## 11. TOXICOLOGICAL INFORMATION: continued

<b>Reproductive Effects</b>	None anticipated from normal handling of this product. Long-term studies in animals have not been performed to evaluate the potential for impairment of fertility or effects on development. However, it has been reported that no teratogenic effect was noted in the offspring of pregnant rats or rabbits given single daily injections of pancuronium at dosages that were 1.6 or 0.2 times that used as the initial intravenous dose in humans. Further, intravascular or intramuscular injections of pancuronium directly into the fetus have been used to induce paralysis for prenatal diagnostic and therapeutic procedures in the second or third trimester of pregnancy. No persistent adverse effects related to such use have been reported, although transient decreased fetal heart rate variability occurs frequently.		
<b>Mutagenicity</b>	Long-term studies to evaluate mutagenic potential have not been performed.		
<b>Carcinogenicity</b>	Long-term studies to evaluate carcinogenic potential have not been performed.		
<b>Carcinogen Lists</b>	<b>IARC:</b> Not listed	<b>NTP:</b> Not listed	<b>OSHA:</b> Not listed
<b>Specific Target Organ Toxicity – Single Exposure</b>	NA		
<b>Specific Target Organ Toxicity – Repeat Exposure</b>	Based on clinical use, possible target organs include the nervous system, respiratory system, muscular system and cardiovascular system.		

## 12. ECOLOGICAL INFORMATION

<b>Aquatic Toxicity</b>	Not determined for product. Information for ingredients is as follows:  LC50(96 hr) = 460 mg/L in Pimephales promelas for benzyl alcohol LC50 = 640 mg/L in Leuciscus idus for benzyl alcohol EC50(24 hr) = 400 mg/L in Daphnia magna for benzyl alcohol EC50 = 95 mg/L in Chlorella pyrenoidosa for benzyl alcohol
<b>Persistence/Biodegradability</b>	Not determined for product. Information for ingredients is as follows:  Benzyl alcohol was degraded over 90% in a 28-day biodegradation assay in sewage sludge.
<b>Bioaccumulation</b>	Not determined for product.
<b>Mobility in Soil</b>	Not determined for product.

**Notes:**

1. LC50: Concentration in water that produces 50% mortality in fish.
2. EC50: Concentration in water that produces 50% inhibition of growth in algae.

## 13. DISPOSAL CONSIDERATIONS

<b>Waste Disposal</b>	All waste materials must be properly characterized. Further, disposal should be performed in accordance with the federal, state or local regulatory requirements.
<b>Container Handling and Disposal</b>	Dispose of container and unused contents in accordance with federal, state and local regulations.

## 14. TRANSPORTATION INFORMATION

<b>ADR/ADG/ DOT STATUS</b>	Not regulated
<b>Proper Shipping Name</b>	NA
<b>Hazard Class</b>	NA
<b>UN Number</b>	NA
<b>Packing Group</b>	NA
<b>Reportable Quantity</b>	NA
<b>ICAO/IATA STATUS</b>	Not regulated
<b>Proper Shipping Name</b>	NA
<b>Hazard Class</b>	NA
<b>UN Number</b>	NA
<b>Packing Group</b>	NA
<b>Reportable Quantity</b>	NA
<b>IMDG STATUS</b>	Not regulated
<b>Proper Shipping Name</b>	NA
<b>Hazard Class</b>	NA
<b>UN Number</b>	NA
<b>Packing Group</b>	NA
<b>Reportable Quantity</b>	NA

Notes: DOT - US Department of Transportation Regulations

## 15. REGULATORY INFORMATION

<b>US TSCA Status</b>	Exempt
<b>US CERCLA Status</b>	Not listed
<b>US SARA 302 Status</b>	Not listed
<b>US SARA 313 Status</b>	Not listed
<b>US RCRA Status</b>	Not listed
<b>US PROP 65 (Calif.)</b>	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
<b>Prevention</b>	Do not breathe vapor or spray Wash hands thoroughly after handling			
<b>Response</b>	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.

<b>Classification(s)</b>	NA
<b>Symbol</b>	NA
<b>Indication of Danger</b>	NA
<b>Risk Phrases</b>	NA
<b>Safety Phrases</b>	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 <sub>50</sub>	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  
Date Prepared: October 19, 2012  
Date Revised: June 02, 2014

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