



## SAFETY DATA SHEET

**Product Name: 1.1% Bacteriostatic Water for Injection, USP**

### 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** 1.1% Bacteriostatic Water for Injection, USP

**Synonyms** NA

### 2. HAZARD(S) IDENTIFICATION

**Emergency Overview** 1.1% Bacteriostatic Water for Injection, USP is an aqueous solution containing benzyl alcohol. In the workplace, this material should be considered potentially irritating to the eyes and respiratory tract. Possible target organs include the central nervous system, gastrointestinal system, and respiratory system.

#### 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

#### **Label Element(s)**

**Pictogram** NA

**Signal Word** NA

**Hazard Statement(s)** NA

**Precautionary Statement(s)** 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.

### 3. COMPOSITION/INFORMATION ON INGREDIENTS

**Active Ingredient Name** Benzyl Alcohol  
**Chemical Formula** C<sub>7</sub>H<sub>8</sub>O

Component	Approximate Percent by Weight	CAS Number	RTECS Number
Benzyl Alcohol	1.1	100-51-6	DN3150000

Non-hazardous ingredients include Water for Injection.

### 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 from this aqueous product. However, when heated, this product may produce combustible vapors.

**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 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

Component	Exposure Limits			
	OSHA-PEL	ACGIH-TLV	AIHA WEEL	Hospira EEL
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 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

Appearance/Physical State	Clear colorless solution
Odor	NA
Odor Threshold	NA
pH	4.5-7.0
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	NA
Partition Coefficient: n-octanol/water	NA
Auto-ignition Temperature	NA
Decomposition Temperature	NA
Viscosity	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).
<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 active ingredient is as follows:

<b>Ingredient(s)</b>	<b>Percent</b>	<b>Test Type</b>	<b>Route of Administration</b>	<b>Value</b>	<b>Units</b>	<b>Species</b>
Benzyl Alcohol	100	LD50	Oral	1660, 1230 1360, 1580 1040, 1940 2500	mg/kg mg/kg mg/kg mg/kg	Rat Mouse Rabbit Guinea Pig
Benzyl Alcohol	100	LD50	Intravenous	53 324	mg/kg mg/kg	Rat Mouse
Benzyl Alcohol	100	LD50	Dermal	2000	mg/kg	Rabbit
Benzyl Alcohol	100	LC50/8hr	Inhalation	>500 1000	mg/m <sup>3</sup> ppm	Rat, Mouse Rat

LD50: Dosage that produces 50% mortality.

LC50 is the concentration in air that produces 50% mortality when inhaled.

<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, concentrations of benzyl alcohol normally used for preservation are generally not associated with serious adverse effects in patients. However, over-exposure to benzyl alcohol by ingestion or inhalation may cause nausea, vomiting, diarrhea, headache, and vertigo. As with many alcohols, serious over-exposure may produce central nervous system and respiratory depression.
<b>Aspiration Hazard</b>	None anticipated from normal handling of this product. However, inadvertent inhalation of product aerosol/vapors may produce irritation with coughing.
<b>Dermal Irritation/ Corrosion</b>	None anticipated from normal handling of this product. Pure benzyl alcohol was considered moderately irritating in a skin irritation study in animals.
<b>Ocular Irritation/ Corrosion</b>	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with redness and tearing.
<b>Dermal or Respiratory Sensitization</b>	None anticipated from normal handling of this product. Rarely, systemic hypersensitivity reactions to benzyl alcohol have been reported during clinical use. In a skin patch study in volunteers exposed to 5 to 10 percent benzyl alcohol in petrolatum for 24-48 hours, about 1 percent of the volunteers gave a positive reaction.

**11. TOXICOLOGICAL INFORMATION: continued**

<b>Reproductive Effects</b>	None anticipated from normal handling of this product. In a short term <i>in vivo</i> bioassay, fifty pregnant CD-1 mice were given 750 mg/kg/day benzyl alcohol in water by gavage on days 6-13 of gestation, and were allowed to deliver. A decrease in birth weights and weight gain, but no malformations, were noted in the pups. Maternal toxicity (death, 19/50) was noted at this dosage.
<b>Mutagenicity</b>	Benzyl alcohol was negative in the Ames Assay for mutagenicity. Further, benzyl alcohol was generally negative or equivocal for genotoxicity in an additional battery of tests. However, benzyl alcohol was considered positive in the chromosome aberration test in Chinese hamster ovary (CHO) cells in the presence of a metabolic activating system.
<b>Carcinogenicity</b>	The results of 2 year gavage studies indicate that there was no evidence of carcinogenic activity in male or female F344/N rats dosed with 200 or 400 mg/kg of benzyl alcohol. Similarly, there was no evidence of carcinogenic activity of benzyl alcohol in male or female B6C3F1 mice dosed with 100 or 200 mg/kg/day for 2 years.
<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 central nervous system, gastrointestinal system, and respiratory system. In clinical use, pre-mature infants over-exposed to benzyl alcohol may exhibit a gasping syndrome characterized by respiratory distress and apneic spells.

**12. ECOLOGICAL INFORMATION**

<b>Aquatic Toxicity</b>	Not determined for the product. Information for ingredients is provided below:  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 the product. Information for ingredients is provided below:  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. However, benzyl alcohol is listed on the TSCA inventory.
<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  
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