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

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

Health Hazards	**Hazard Class**	**Hazard Category**
	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_7H_8O

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

	Exposure Limits			
Component	**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

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).
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
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/m3 ppm	Rat, Mouse Rat

LD50: Dosage that produces 50% mortality.
LC50 is the concentration in air that produces 50% mortality when inhaled.

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, 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 product central nervous system and respiratory depression.
Aspiration Hazard	None anticipated from normal handling of this product. However, inadvertent inhalation of product aerosol/vapors may produce irritation with coughing.
Dermal Irritation/ Corrosion	None anticipated from normal handling of this product. Pure benzyl alcohol was considered moderately irritating in a skin irritation study in animals.
Ocular Irritation/ Corrosion	None anticipated from normal handling of this product. However, inadvertent contact of this product with eyes may produce irritation with redness and tearing.
Dermal or Respiratory Sensitization	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

Reproductive Effects	None anticipated from normal handling of this product. In a short term *in vivo* 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.
Mutagenicity	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.
Carcinogenicity	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.
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 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

Aquatic Toxicity	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
Persistence/Biodegradability	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.
Bioaccumulation	Not determined for product.
Mobility in Soil	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

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. However, benzyl alcohol is listed on the TSCA inventory.
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
Date Prepared:	October 17, 2012
Date Revised:	June 02, 2014

Disclaimer:

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