

MATERIAL SAFETY DATA SHEET

Product Name: Bacteriostatic Water 1.1% for Injection, USP

1. CHEMICAL PRODUCT AND COMPANY INFORMATION

Manufacturer Name And Address Hospira Inc.
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Lake Forest, Illinois USA
60045

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Hospira, Inc., Non-Emergency 224-212-2000

Product Name Bacteriostatic Water 1.1% for Injection, USP

Synonyms NA

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name Benzyl Alcohol

Chemical Formula C₇H₈O

Preparation Non-hazardous ingredients include Water for Injection.

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

3. HAZARD INFORMATION

Carcinogen List

Substance	IARC	NTP	OSHA
Benzyl Alcohol	Not Listed	Not Listed	Not Listed

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, respiratory system, and eyes.

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 known from occupational exposure. Inhalation of product aerosols or inadvertent splashes to the eyes may produce irritation. 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.

Medical Conditions Pre-existing hypersensitivity to benzyl alcohol; pre-existing central nervous system,

Product Name: Bacteriostatic Water 1.1% for Injection, USP



Aggravated by Exposure gastrointestinal system, respiratory system, or eye ailments.

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.
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 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

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	Type	Exposure limits			
		mg/m3	ppm	µg/m3	Note
Benzyl Alcohol	AIHA WEEL	N/A	10	N/A	8-hr TWA

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) and an organic vapor cartridge is recommended under conditions where airborne aerosol concentrations are not expected to be excessive. 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	Liquid
Color	Clear, colorless
Odor	NA
Odor Threshold:	NA
pH:	4.5 - 7.0
Melting point/Freezing point:	NA
Initial Boiling Point/Boiling Point Range:	NA
Evaporation Rate:	NA
Flammability (solid, gas):	NA
Upper/Lower Flammability or Explosive Limits:	NA
Vapor Pressure:	NA
Vapor Density:	NA
Specific Gravity:	NA
Solubility:	NA
Partition coefficient: n-octanol/water:	NA
Auto-ignition temperature:	NA
Decomposition temperature:	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 ingredients 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

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.

Reproductive Effects 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

Product Name: Bacteriostatic Water 1.1% for Injection, USP



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.
Target Organ Effects	During occupational use, possible target organs include the central nervous system, gastrointestinal system, respiratory system, and eyes. 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 <i>Pimephales promelas</i> for benzyl alcohol LC50 = 640 mg/L in <i>Leuciscus idus</i> for benzyl alcohol EC50(24 hr) = 400 mg/L in <i>Daphnia magna</i> for benzyl alcohol EC50 = 95 mg/L in <i>Chlorella pyrenoidosa</i> 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.

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
IMDG STATUS:	Not regulated

Product Name: Bacteriostatic Water 1.1% for Injection, USP**ICAO/IATA STATUS:** Not regulated**Transport Comments:** None**15. REGULATORY INFORMATION****USA Regulations**

Substance	TSCA Status	CERCLA Status	SARA 302 Status	SARA 313 Status	PROP 65 Status
Benzyl Alcohol	Listed	Not Listed	Not Listed	Not Listed	Not Listed

RCRA Status Not Listed
U.S. OSHA Target Organ Toxin
Classification Possible Irritant

GHS *In the EU, classification under GHS/CLP does not apply to certain substances and mixtures, such as
Classification medicinal products as defined in Directive 2001/83/EC, which are in the finished state, intended for the final user:

Hazard Class Not Applicable

Hazard Category Not Applicable

Signal Word Not Applicable

Symbol Not Applicable

Prevention P260 - Do not breathe dust/fume/gas/mist/vapors/spray.

Hazard Statement Not Applicable

Response: 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. Wash hands after handling.

Get medical attention if you feel unwell.

EU Classification*

*Medicinal products are exempt from the requirements of the EU Dangerous Preparations Directive. Information provided below is for the pure drug substance Benzyl Alcohol

Classification(s): Not Applicable

Symbol: Not Applicable

Indication of Danger: Not Applicable

Risk Phrases: Not Applicable

Safety Phrases: S23 - Do not breathe vapor.
S24/25 - Avoid contact with skin and 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
LD50	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
TSCA	Toxic Substance Control Act
TWA	8-hour Time Weighted Average

MSDS Coordinator: Hospira GEHS

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