1. CHEMICAL PRODUCT AND COMPANY INFORMATION

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
Hospira, Inc., Non-Emergency 224 212-2055

Product Name
1.1% Bacteriostatic Water for Injection, USP

Synonyms
NA

2. COMPOSITION/INFORMATION ON INGREDIENTS

Active Ingredient Name
Benzyl Alcohol

Chemical Formula
C₇H₈O

<table>
<thead>
<tr>
<th>Component</th>
<th>Approximate Percent by Weight</th>
<th>CAS Number</th>
<th>RTECS Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>1.1</td>
<td>100-51-6</td>
<td>DN3150000</td>
</tr>
</tbody>
</table>

Non-hazardous ingredients include Water for Injection.

3. HAZARD INFORMATION

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
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 produce central nervous system and respiratory depression.

Medical Conditions Aggravated by Exposure
Pre-existing hypersensitivity to benzyl alcohol; pre-existing central nervous system, gastrointestinal system, respiratory system, or eye ailments.

Carcinogen Lists:
IARC: Not listed
NTP: Not listed
OSHA: Not listed
Product Name: 1.1% Bacteriostatic Water for Injection, USP

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 fire fighting 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.

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

<table>
<thead>
<tr>
<th>Component</th>
<th>OSHA-PEL</th>
<th>ACGIH-TLV</th>
<th>AIHA WEEL</th>
<th>Hospira EEL</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>8-hr TWA: Not Established</td>
<td>8-hr TWA: Not Established</td>
<td>8-hr TWA: 10 ppm</td>
<td>8-hr TWA: Not Established</td>
</tr>
</tbody>
</table>

**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) 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

<table>
<thead>
<tr>
<th>Property</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Appearance/Physical State</strong></td>
<td>Clear colorless solution</td>
</tr>
<tr>
<td><strong>Odor</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Odor Threshold</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>pH</strong></td>
<td>4.5-7.0</td>
</tr>
<tr>
<td><strong>Melting point/Freezing point</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Initial Boiling Point/Boiling Point Range</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Evaporation Rate</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Flammability (solid, gas)</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Upper/Lower Flammability or Explosive Limits</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Vapor Pressure</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Vapor Density (Air =1)</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Evaporation Rate</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Specific Gravity</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Solubility</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Partition coefficient: n-octanol/water</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Auto-ignition temperature</strong></td>
<td>NA</td>
</tr>
<tr>
<td><strong>Decomposition temperature</strong></td>
<td>NA</td>
</tr>
</tbody>
</table>
Product Name: 1.1% Bacteriostatic Water for Injection, USP

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:

<table>
<thead>
<tr>
<th>Ingredient(s)</th>
<th>Percent</th>
<th>Test Type</th>
<th>Route of Administration</th>
<th>Value</th>
<th>Units</th>
<th>Species</th>
</tr>
</thead>
<tbody>
<tr>
<td>Benzyl Alcohol</td>
<td>100</td>
<td>LD50</td>
<td>Oral</td>
<td>1660, 1230</td>
<td>mg/kg</td>
<td>Rat, Mouse, Rabbit, Guinea Pig</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1360, 1580</td>
<td>mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1040, 1940</td>
<td>mg/kg</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>2500</td>
<td>mg/kg</td>
<td></td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100</td>
<td>LD50</td>
<td>Intravenous</td>
<td>53</td>
<td>mg/kg</td>
<td>Rat, Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>324</td>
<td>mg/kg</td>
<td></td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100</td>
<td>LD50</td>
<td>Dermal</td>
<td>2000</td>
<td>mg/kg</td>
<td>Rabbit</td>
</tr>
<tr>
<td>Benzyl Alcohol</td>
<td>100</td>
<td>LC50/8hr</td>
<td>Inhalation</td>
<td>&gt;500</td>
<td>mg/m3</td>
<td>Rat, Mouse</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td>1000</td>
<td>ppm</td>
<td></td>
</tr>
</tbody>
</table>

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

Aspiration Hazard
None anticipated from normal handling of this product. 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. 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 malformations, were noted in the pups. Maternal toxicity (death, 19/50) was noted at this dosage.
11. TOXICOLOGICAL INFORMATION: continued

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 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

<table>
<thead>
<tr>
<th>DOT STATUS</th>
<th>Not regulated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proper Shipping Name</td>
<td>NA</td>
</tr>
<tr>
<td>Hazard Class</td>
<td>NA</td>
</tr>
<tr>
<td>UN Number</td>
<td>NA</td>
</tr>
<tr>
<td>Packing Group</td>
<td>NA</td>
</tr>
<tr>
<td>Reportable Quantity</td>
<td>NA</td>
</tr>
<tr>
<td>ICAO/IATA STATUS</td>
<td>Not regulated</td>
</tr>
<tr>
<td>Proper Shipping Name</td>
<td>NA</td>
</tr>
<tr>
<td>Hazard Class</td>
<td>NA</td>
</tr>
<tr>
<td>UN Number</td>
<td>NA</td>
</tr>
<tr>
<td>Packing Group</td>
<td>NA</td>
</tr>
<tr>
<td>Reportable Quantity</td>
<td>NA</td>
</tr>
<tr>
<td>IMDG STATUS</td>
<td>Not regulated</td>
</tr>
<tr>
<td>Proper Shipping Name</td>
<td>NA</td>
</tr>
<tr>
<td>Hazard Class</td>
<td>NA</td>
</tr>
<tr>
<td>UN Number</td>
<td>NA</td>
</tr>
<tr>
<td>Packing Group</td>
<td>NA</td>
</tr>
<tr>
<td>Reportable Quantity</td>
<td>NA</td>
</tr>
</tbody>
</table>

Notes: DOT - US Department of Transportation Regulations

15. REGULATORY INFORMATION

<table>
<thead>
<tr>
<th>US TSCA Status</th>
<th>Exempt. However, benzyl alcohol is listed on the TSCA inventory.</th>
</tr>
</thead>
<tbody>
<tr>
<td>US CERCLA Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>US SARA 302 Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>US SARA 313 Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>US RCRA Status</td>
<td>Not listed</td>
</tr>
<tr>
<td>US PROP 65 (Calif.)</td>
<td>Not listed</td>
</tr>
</tbody>
</table>


U.S. OSHA Classification

Possible Irritant
Target Organ Toxin

GHS 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 | NA |
| Hazard Category | NA |
| Symbol | NA |
| Signal Word | NA |
| Hazard Statement | NA |
| Prevention | Do not breathe vapor or spray. |
| 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. |
Product Name: 1.1% Bacteriostatic Water for Injection, USP

15. REGULATORY INFORMATION: continued

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
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
Date Prepared: 03/23/2011

Disclaimer:
The information and recommendations contained herein are based upon tests believed to be reliable. However, Hospira does not guarantee their accuracy or completeness NOR SHALL ANY OF THIS INFORMATION CONSTITUTE A WARRANTY, WHETHER EXPRESSED OR IMPLIED, AS TO THE SAFETY OF THE GOODS, THE MERCHANTABILITY OF THE GOODS, OR THE FITNESS OF THE GOODS FOR A PARTICULAR PURPOSE. Adjustment to conform to actual conditions of usage may be required. Hospira assumes no responsibility for results obtained or for incidental or consequential damages, including lost profits, arising from the use of these data. No warranty against infringement of any patent, copyright or trademark is made or implied.